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Assessment of the Capacities of Food Safety Laboratories in Palestine

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Dedication

This work is dedicated with sincere gratitude to my dear parents and to my beloved wife, Mrs. Hiba Omareya, who has been a constant source of support and encouragement during the challenges of graduate studies and life. I am truly thankful for having you in my life.

The Researcher

Adeeb Nawahda

Declaration

I certify that this thesis submitted for the degree of master, is the result of my own research, except where otherwise acknowledged, and this thesis has not been submitted for the higher degree to any other university or institution.

Adeeb Ismael Amin Nawahda

Signed: ……Adeeb…….

Date : 22/12/2019

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This accomplishment would not have been possible without them.

With all sincerity, love, and respect.

ABSTRACT

In Palestine, the food industry and agribusiness are growing and expanding in scale and diversity responding to the continually changing market demands. Thus, to provide consumers with safe products, laboratories of food safety play a crucial role and form the basis of the national food control system. The aim of this research was to assess the testing practices and the compliance of the main food safety laboratories in Palestine (seven laboratories in West Bank and two laboratories in Gaza Strip) with the internationally recognized standards and guidelines.

To achieve the purpose of the study, the researcher used questionnaires focusing mainly on the following aspects; quality assurance and quality control, testing procedure, available devices and equipment, facilities and premises, personnel, handling of samples, and main barriers. In addition to that, the researcher used structured interviews with three national food control authorities, they were conducted to survey their practices related to testing of food safety and their relationship with local food safety laboratories.

The collected data and information were processed and analyzed using the SPSS program. Additionally, SWOT analysis was used to get a better understanding of the practices of the targeted laboratories. Key findings are summarized as follows: (i) Five out of the nine working laboratories in Palestine were locally accredited by the Ministry of National Economy (MONE) and the accreditation did not cover all performed food tests. While other laboratories were providing service without any accreditation. (ii) Most of the assessed laboratories were not fulfilling adequately the requirements of the recognized international standards and guidelines such as ISO17025. (iii) No sub-contracting analysis between laboratories (no parallel integration). (iv)More than half of the laboratories had participated in national or international inter-laboratory proficiency tests with (66.7%) of agreement. (v) Only five laboratories had the necessary equipment to perform most of the chemical, microbiological, and physical food safety tests, while the others performed mainly microbiological or physical tests. (vi)Most laboratories, in terms of facilities and premises, were well designed but did not have enough space to facilitate and expand their work. (vii) Six of the nine laboratories studied suffered from lacking staff with and 5 suffered from lack of sufficient training for lab staff. (viii) More than half of the laboratories introduced

sampling services following procedures and instructions. (ix) All of the laboratories performed procedures for traceability of samples from reception until reporting of results, but only three laboratories used an electronic LIMS (Laboratory Information Management System) for traceability. (x) The laboratories had faced many gaps due to managerial and technical reasons, such as: (small scale of businesses, the limited geographical distribution of laboratories, inability to perform certain food tests, insufficient space, equipment maintenance difficulties, no periodic maintenance, insufficient lab staff, insufficient training, insufficient equipment, and no specific turnaround time (TAT) for tests. (xi) The laboratories faced many external obstacles such as (occupation, frequent closures and access restrictions, high costs of equipment and materials, unavailability of some materials, power cuts, no existing international accreditation body, and no licensing authority for food laboratories). (xii) On the other hand, two out of the three national control authorities did not have any food safety laboratories. There is a lack of a clear sampling plan specifying the number of samples and frequency of sampling for food establishments. Also, there was no data communication or warnings from food safety laboratories about risks and history of tested food samples in general.

Several recommendations targeting both the food safety laboratories and the national food control authorities are presented in this thesis. These recommendations focused mainly on the sustainability of the service, strengthening the testing competence and leveling up the skills of the laboratory staff.

According to the best knowledge of the researcher, this study is the first of its type in Palestine and no previous studies have been undertaken to assess the competence of the food safety laboratories. Thus, this research gives a better understanding of the current situation and sheds light on the number of emerging concerns related to the national food safety system.

Keywords: Assessment, Food safety laboratory, Control authority, Food safety tests, Sampling, Accreditation, Proficiency tests, Managerial gaps, Technical gaps, Capacity.

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GLOSSARY OF TERMS

Assessment: "a rigorous assessment, conducted by an independent science-based organization, to assure the overall capability and competency of a laboratory and its quality management systems". (The Partnership for Food Protection Laboratory Task Group, 2013)

Accreditation: "evaluation of how food safety testing laboratories met the regulatory requirements applicable to its accredited area of activity and/or accredit". (European Food-SAT, 2017)

Capacity: "Capacity of laboratories for examining and analyzing food samples in terms of human, financial, managerial, technical and material resources ". (Morse, et al., 2018).
Another definition: The ability of individuals, organizations and systems to perform functions effectively, efficiently and sustainably (UNDP, 1998a).

Control Authority: "National authority have the responsibility of protecting public health by reducing the risk of food-borne disease and providing food safety education and information to consumers and the food industry ". (FAO, 2008)

Food Control: a mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labelled as prescribed by law. (FAO/WHO, 2003).

Food Safety Laboratory: "Laboratory that performs safety tests on a food product, ingredients, in-process samples and associated environmental samples for chemical and microbiological parameters". (International Accreditation Service, 2015)

Food Safety Tests: "Tests provide the assurance that food is acceptable for human consumption according to its intended use". (FSSAI, 2017)

Proficiency Tests: "Tests determine the performance of individual laboratories for specific tests or measurements and is used to monitor laboratories' continuing performance". (International Accreditation Service, 2015)

Sampling: "A predetermined procedure for the selection, withdrawal, preservation and preparation of the sample". (FAO, 2005)

Quality System: "The organizational structure, responsibilities, procedures, processes and resources for implementing quality management". (International Accreditation Service, 2015)

Standard Operating Procedure SOP: "A document that specifies or describes how an activity is to be performed. It may include methods to be used and a sequence of operations". (International Accreditation Service, 2015)

Internal Audit: "A formal review of the performance of a management system conducted by laboratory personnel from outside of the laboratory or department under review". (International Accreditation Service, 2015)

Calibration: "Comparison and adjustment to a standard of known accuracy. The set of operations which establish, under specific conditions, the relationship between values of

quantities by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards". (International Accreditation Service, 2015)

Certified Reference Material (CRM): "Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure that establishes metrological traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence". (International Accreditation Service, 2015)

ABBREVIATIONS

APCC:	Analysis, Poison Control and Calibration Center
CPHL:	Central Public Health Laboratory
CRM:	Certified Reference Material
CVL:	Central Veterinary Laboratory
FAO:	Food and Agriculture Organization
FSL:	Food Safety Laboratories
GC:	Gas Chromatography
GLP:	Good Laboratory Practices
HPLC:	High Performance Liquid Chromatography
ICP-MS:	Inductively coupled plasma mass spectrometry
ISO:	International Standards Organization
LIMS:	Laboratory Information Management System
MOA:	Ministry of Agriculture
MOH:	Ministry of Health
MONE:	Ministry of National Economy
PALAC:	Palestinian Accreditation
PFSL:	Palestinian Food Safety Laboratories
PSI:	Palestinian Standards Institutions
QC:	Quality Control
SOP:	Standard Operation System
SPS:	Sanitary and Phytosanitary
SWOT:	Strengths, weaknesses, opportunities and threats
TAT:	Turn Around Time
TLC:	Testing Laboratories Center
UV-Vis:	Ultraviolet–Visible Spectrophotometry
WHO:	World Health Organization

CHAPTER ONE: INTRODUCTION

1.1 Background Information

Food Safety and Consumer Protection

The terms of food safety and food quality are sometimes confusing. Food safety refers to all those hazards, whether chronic or acute, that may make food injurious to the health of the consumer. It is not negotiable. Quality includes all other attributes that influence a product's value to the consumer. This includes negative attributes such as spoilage, contamination with filth, discoloration, off-odors and positive attributes such as the origin, color, flavor, texture, and processing method of the food. This distinction between safety and quality has implications for public policy and it influences the nature and content of the food control system most suited to meet predetermined national objectives.

The foremost responsibility of food control is to enforce the food law(s) protecting the consumer against unsafe, impure and fraudulently presented food by prohibiting the sale of food not of nature, substance or quality demanded by the purchaser.

Confidence in the safety and the integrity of the food supply is an important requirement for consumers. Foodborne disease outbreaks involving agents such as *Escherichia coli, Salmonella,* and chemical contaminants highlight problems with food safety and increase public anxiety that modern farming systems, food processing and marketing do not provide adequate safeguards for public health. Factors that contribute to potential hazards in foods include improper agricultural practices; poor hygiene at all stages of the food chain; lack of preventive controls in food processing, and preparation operations; misuse of chemicals; contaminated raw materials, ingredients and water; inadequate or improper storage, etc.

Specific concerns about food hazards have usually focused on:

- Microbiological hazards;
- Pesticide residues;

- Misuse of food additives;
- Chemical contaminants, including biological toxins; and
- Adulteration.

Consumers expect protection from hazards occurring along the entire food chain, from primary producers through consumers (often described as the ***farm-to-table*** continuum). Protection will only occur if all sectors in the chain operate in an integrated way, and food control systems address all stages of this chain.

As no mandatory activity of this nature can achieve its objectives fully without the cooperation and active participation of all stakeholders *e.g.* farmers, industry, and consumers, the term ***Food Control System*** is used to describe the integration of a mandatory regulatory approach with preventive and educational strategies that protect the whole food chain. Thus, an ideal food control system should include effective enforcement of mandatory requirements, along with training and education, community outreach programs and promotion of voluntary compliance. The introduction of preventive approaches such as the Hazard Analysis Critical Control Point System (HACCP) has resulted in the industry taking greater responsibility for and control of food safety risks. Such an integrated approach facilitates improved consumer protection, effectively stimulates agriculture and the food processing industry, and promotes domestic and international food trade. (FAO/WHO, 2003).

The conclusion of the Uruguay Round of Multilateral Trade Negotiations in Marrakech led to the establishment of the WTO on 1 January 1995, and the coming into force of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). Both these Agreements are relevant in understanding the requirements for food protection measures at the national level, and the rules under which food is traded internationally.

The SPS Agreement confirms the right of WTO member countries to apply measures to protect human, animal and plant life and health. The Agreement covers all relevant laws, decrees, regulations; testing, inspection, certification and approval procedures; and packaging and labeling requirements directly related to food safety. Member States are asked to apply only those measures for protection that are based on scientific principles, only to the extent necessary, and not in a manner that may constitute a disguised restriction on international trade. The Agreement encourages the use of

international standards, guidelines or recommendations where they exist and identifies those from Codex (relating to food additives, veterinary drugs and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practices), to be consistent with provisions of SPS. Thus, the Codex standards serve as a benchmark for comparison of national sanitary and phytosanitary measures. While it is not compulsory for the Member States to apply Codex Standards, it is in their best interests to harmonize their national food standards with those elaborated by Codex.

The principal objectives of national food control systems are:

1. Protecting public health by reducing the risk of foodborne illness;
2. Protecting consumers from unsanitary, unwholesome, mislabeled or adulterated food; and
3. Contributing to economic development by maintaining consumer confidence in the food system and providing a sound regulatory foundation for domestic and international trade in food.

While the components and priorities of a food control system will vary from country to another, most systems will typically comprise the following components:

1. Food Law and Regulations;
2. Food Control Management;
3. Inspection Services;
4. ***Laboratory Services***: Food Monitoring and Epidemiological Data; and
5. Information, Education, Communication and Training.

Food safety laboratories (FSL)

Food safety laboratories are essential component of a food control system. The establishment of laboratories requires considerable capital investment and they are expensive to maintain and operate. Therefore, careful planning is necessary to achieve optimum results. The number and location of the laboratories should be determined in relation to the objectives of the system and the volume of work. If more than one laboratory is required, consideration should be given to apportioning the analytical work to achieve the most effective coverage of the food analyses to be performed and

also to have a central reference laboratory equipped for sophisticated and reference analyses.

All food safety laboratories may not be under the control of one agency or ministry, and a number could be under the jurisdiction of the states, provinces and local authorities. The Food Control Management should, however, lay down the norms for food safety laboratories and monitor their performance.

Food safety laboratories should have adequate facilities for physical, microbiological and chemical analyses. In addition to simple routine analysis, the laboratories can be equipped with more sophisticated instruments, apparatus and library facilities as required. It is not only the type of equipment that determines the accuracy and reliability of analytical results but also the qualification and skill of the analyst and the reliability of the method used. The analytical results of a food safety laboratory are often used as evidence in a court of law to determine compliance with regulations or standards of the country. It is, therefore, necessary that utmost care is taken to ensure the efficient and effective performance of the laboratory. The introduction of analytical quality assurance programs and accreditation of the laboratory by an appropriate accreditation agency within the country or from outside enables the laboratory to improve its performance and to ensure reliability, accuracy, and repeatability of its results. Prescription of official methods of sampling and analysis also supports this effort.

Analysis of food samples for physical, chemical, and microbiological contamination is needed to:

1- Verify the safety and the quality of food (including compositional characteristics, nutrition values, adulteration, presence of contaminants, etc.) that is produced domestically, imported, and/or exported,
2- Enable appropriate action to be taken to protect the health of consumers whenever it is necessary by producers and control authority,
3- Increase the consumer confidence on food safety control system.

An important element of the national food control system is its integration in a national food safety system so that it links between food contamination and food borne diseases

can be established and analyzed. Access to reliable and current intelligence on the incidence of foodborne illness is critical. The laboratory facilities for this type of activity are generally situated outside the food control agencies. It is essential, however, that effective linkages are established between food control agencies and the public health system including epidemiologists and microbiologists. In this way, information on foodborne diseases may be linked with food monitoring data, and lead to appropriate risk-based food control policies. This information includes annual incidence trends, identification of susceptible population groups, identification of hazardous foods, identification and tracking of causes of foodborne diseases, and the development of early warning systems for outbreaks and food contamination.

Nations used to implement special legislation and regulations to assess the capacity of food safety laboratories depending on a range of factors; which is concentrated on the internal characteristics of individual laboratories to determine their ability to perform routine food safety analysis and to deal with emergency cases, such as: "the quantity and quality of deployed equipment and instrument, the skills and qualifications of staff, the procedures and methods used for the analysis...etc.". Adding to that, these legislations and regulations would ensure that these laboratories have the internal capacity needed to food control, and to clarify the procedures or framework of their activities in the area of their work.

The Palestinian National Authority (PNA) adopted a multi-organization system for food control; where the responsibility of food safety and law enforcement carried out by some ministries and governmental organizations (such as Ministry of National Economy (MONE), Ministry of Agriculture (MOA), Ministry of Health (MOH), Municipalities and the Palestine Standards Institution (PSI). Moreover, there are nine Palestinian food safety laboratories (PFSL), five of them are governmental laboratories and four belong to the privet sector. PFSL involved in food safety testing for several customers such as government parties, factories, and individuals.

1.2 Problem Statement and Research Questions

In Palestine, it is the joint responsibility of the government, private sector, civil society, and all related sectors to ensure that: "consumers have the right to expect that all food available in the market is safe and of the expected quality" is fulfilled. Even though

reliable laboratory testing capacity functioning up to the international standards is considered one of the most important prerequisites to ensure proper risk-based monitoring and control of food safety, as a consumer right from one side, and as a trade enabler from the other side. Although, there is no clear understanding and evidence whether the testing capacities of the Palestinian food safety laboratories (PFSL) are capable to perform the necessary tests with the required credibility to ensure effective monitoring and management of food safety-related risks. There is also no information available on whether the laboratories are effectively linked to the mandated control authorities to inform food safety risk analysis and inspection.

The research seeks to answer the following questions:

1- What are the main tests and equipment available at PFSL?
2- What are the local or the international accredited food safety laboratories, and what are the accredited food safety tests at these laboratories?
3- Do the PFSL implement quality system procedures for laboratories effectively?
4- What are the main methods and procedures applied at PFSL related to analyses?
5- What are the main managerial capacity gaps at PFSL?
6- What are the main technical capacity gaps at PFSL?
7- What are the main procedures that control authorities used to test food safety? And what are the relationship between control authorities and PFSL?

1.3 Justifications

1- Ensuring the safety of food, which became an essential requirement for public health and food marketing due to the significant rise in consumers' awareness and demands, in addition to food market diversity. Hence public health efforts all over the world are intensifying their efforts to improve their diagnostic and to control capacities.
2- Although Palestine endorsed the first-ever National Strategy for Food Safety and increasing the need for laboratories that meet international standards, it is

not clear if that existing food safety laboratories' capacities are compliant with international standards.

3- Risk base inspection, food safety control, and its enhancement actions are not clear.
4- The results of this study are in line with NSFS and will highlight the main areas of enhancement regarding food safety laboratories.
5- The researcher's expertise and current profession relatively match the need for a better understanding of food safety laboratory capacities and enhancement needs.

1.4 Objectives

The research seeks to achieve the following objectives:

1. To assess the status of food safety laboratory capacities and services in Palestine referring to the international standards.
2. To identify the capacity gaps and needs in the area of food safety laboratories.
3. To analyze the current situation considering international norms and practices and define actionable recommendations.
4. To assess whether PFSL are linked to risk analysis and food inspection.
5. To increase decision-makers' awareness about the role of food safety laboratories within a national food safety system.
6. To provide objective data to national decision-makers for planning and implementing laboratory capacity strengthening activities.
7. To introduce proposed methods for improving the managerial and technical capacity of PFSL.

1.5 Boundaries

The research boundaries are as follows:

- This study was conducted in 2018-2019.It took place in the West Bank and Gaza Strip.
- Targeted groups:

1. PFSL (including governmental and private laboratories that provide services to the food factories, individuals and public sector) that are involved in food analysis (physical, chemical, and microbiological).
2. Control authorities carrying out official inspection duties and sampling relating to food safety.

CHAPTER TWO: LITERATURE REVIEW

Monitoring of contamination at relevant stages is very important, especially in the food chain and the timely surveillance of foodborne disease, where decisions would be taken of food control services. (Mwamakamba, et al. 2012)

Laboratory analysis features heavily in the establishment of food control systems by contributing to the assessment of the level of exposure to potential risks in the food chain and through compliance assessment. Laboratory services can be provided from both within the government and the private sector and there are good working examples of both types of operation in many parts of the world. (Brereton, et al. 2014)

In order to perform analyses to internationally recognized standards, considerable investment in staff and infrastructure is required. Demonstration of competence in sampling and analysis through the audit of procedures and accreditation is essential and must be included in any capacity building requirements if the resulting analyses are to be accepted at export. Training in methodology and techniques for analyzing food are only part of the training requirements needed for food analysts to be able to verify compliance with food standards. (Brereton, et al. 2014)

The method requirement for testing will be dictated by the standards/legislation relevant to the intended market. Whereas the specific reference method may change, there is general commonality on the types of analytes that are required to be tested. These will generally fall in one of the following headings: "Food composition, Food labeling, Food pathogens, Trace elements/heavy metals, Natural toxicants (e.g. mycotoxins), Food contact materials, Pesticides, antibiotic residues, and GM food and feeds". (Brereton, et al. 2014)

2.1 General Requirements for the Competence of Food Safety Testing Laboratories

2.1.1 Quality System

The quality system is concerned with everything that goes on in the laboratory, which may affect "Quality". Each member of the staff involved in the quality system must be

clear about what they are expected to do, know how to do it, and be able to show that they had done it properly. Documentation is a major feature of the quality system. Formulation of a Quality system should contain three essential components (WHO, 2011):

1. Prevention, which requires an orderly program of planning and positive actions before or during analysis to ensure that all analytical systems are performing appropriately, easy calibration and maintenance of instruments use of reference materials and training.
2. Assessment, a form of control that includes periodic checks on analyst performance.
3. Correction, an action taken to determine the cause (s) of quality defects and to re-establish proper functioning of analytical operations e.g. troubleshooting to correct malfunctioning equipment, re-evaluation of methodology and re-training.

Each laboratory with a quality system should have a manual that documents the operations of the laboratory. Quality Control / Quality Assurance procedures should be documented at the laboratory, including "preparation, extraction, equipment calibration and maintenance process control, and standards for approving/rejecting results".

2.1.2 Internal Audits

Internal audits should be performed by food safety laboratories at regular intervals to provide information on whether the management system complies with the laboratory's management system standards, including laboratory operations and ISO 17025 specifications; and will be efficiently implemented and maintained. (ISO/IEC 17025:2017)

The food safety laboratories should plan, develop, and maintain an audit program that includes frequency, methods, responsibilities, planning and reporting requirements, taking into consideration the importance of the relevant laboratory activities, changes affecting the laboratory, the audit criteria and scope for each audit, and the results of previous audits. Also, implement appropriate corrective actions and retain records, and ensure that the results of the audits are reported to relevant management. (ISO/IEC 17025:2017)

2.1.3 Accreditation

Laboratory accreditation is a "procedure in which certification of competency and/or credibility is presented, whereby a national accreditation body formally recognizes laboratory as competent to carry out specific tests or calibrations and compliant with ISO 17025 standard. It is based on the audit carried out by an independent external body supported by highly competent technical experts".

Most accreditation firms issue the accreditation as a granted certificate for laboratories in a specific set of tests that achieved the following assessment examinations "the analytical methods in use; facilities, equipment, reagents and environment; staff adequacy, competency and training program; calibration, traceability (standards, reference materials); quality control procedures (internal/external); and quality system management, documentation and records" (Kocourek, 2012)

There are several internationally accepted standards applicable to laboratories (Table1) and many of these have been developed by ISO. Standards ensure desirable characteristics of products and services such as quality, safety, reliability, efficiency, and reproducibility. ISO standards provide a technical base for health, safety and conformity assessment (WHO, 2011). One of the main accreditation standards utilized by food safety laboratories throughout the world is ISO/IEC 17025:2017.

Table (2.1): International standards applicable to laboratories

International Standard	Description
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO 15189	Medical laboratories – particular requirements for quality and competence
ISO/IEC 17043	Conformity assessment – general requirements for proficiency testing
ISO 13528	Statistical methods for use in proficiency testing by interlaboratory comparison
OECD GLP	OECD principles on good laboratory practice
ISO Guide 34	General requirement for the competence of reference material producers
ISO 8402	Quality management and quality assurance – vocabulary
ISO 19011	Guidelines for quality and/or environmental management system auditing
ISO 9001	Quality management systems – requirements

Source: World Health Organization (2011). Laboratory Quality Standards and their Implementation, WHO Library, p3. (ISBN 978 92 9022 397 9)

Investment in laboratory accreditation for the food safety laboratories will add a value to the mission of protecting the public health by providing greater laboratory capacity of quality data submitted to food control authorities.

The international standard that national and international accreditation bodies use for accrediting testing laboratories is ISO 17025. The laboratory obtains accreditation from an internationally recognized body that guarantees acceptance of test results in various countries of the world.

Acceptance of an accreditation body into the International Laboratory Accreditation Cooperation (ILAC) is dependent upon being successfully evaluated by peers from other accreditation bodies in accordance with the relevant rules and procedures contained in ILAC publications. Each accreditation body that is a signatory to the ILAC MRA commits to: Maintain conformity with the current version of ISO/IEC 17011 (Requirements for accreditation bodies accrediting conformity assessment bodies). ILAC Guidance documents for accreditation bodies and accredited organizations may provide information on the interpretation of accreditation criteria for specific applications. These guidelines have been prepared to assist accreditation bodies to set up training courses that are in line with international practice and which will enable them to generate the lead assessors and technical assessors

In Palestine, there is a local accreditation body (PALAC) affiliated to the Ministry of National Economy that accredits food laboratories based on the principles of international standard ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories), this standard focused on "laboratory operations and management". But PALAC is recognized only locally, so it seeks to be recognized by ILAC.

2.1.4 Proficiency Test

Proficiency Testing (PT) is defined as "determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple samples to members of a group of laboratories for analysis and/or

identification; the program then compares each laboratory's results with those of other laboratories in the group and/or with an assigned value" (Armbruster and Donnely, 2016).

Proficiency Testing by inter-laboratory comparisons is used to "determine the performance of individual laboratories for specific tests or measurements, and to monitor the continuing performance of laboratories. Participation in proficiency testing schemes provides laboratories with an objective means of assessing and demonstrating the reliability of the data they are producing, where one of the main uses of proficiency testing schemes is to asses laboratories' ability to perform tests competently" (International Organization for Standardization, 1997).

Proficiency Testing purposed to help food safety laboratories to detect and cure the unacceptable large inaccuracy in the reported results, whereby participating in the proficiency testing, laboratories would get some benefits, "i.e., support of (self) confidence for laboratory management and analysts, comparison (benchmarking) with other laboratories, verification of methods on use – bias detection, identification of difficulties, improvement – innovation, participation is required by the law (e.g. official control laboratories), and requirement of the accreditation" (Kocourek, 2012).

In Palestine, the Quality Center for Medical Laboratories (EQAS) at Al-Quds University launched the external control project for food safety and drinking water from microbial contamination in Palestine at the beginning of 2019 with the support of the Food and Agriculture Organization of the United Nations (FAO) in cooperation with the Accreditation Unit PALAC at MONE. The Quality Center for Medical Laboratories, which is supervised by the Faculty of Health Professions at Al-Quds University, is the only center in Palestine that provides this service in the West Bank area and supervises the performance of all the licensed laboratories in the West Bank.

2.1.5 Methods of Analysis

Food safety laboratories must use test methods that achieve the needs of the customers. Since not all the national laboratories could have international/national accreditation, these methods should comply with the essential/critical elements of regulatory

requirements, international, or at least the national standards (International Accreditation Service, 2015).

Only official methods should be used by food safety laboratories depending on the requirement of the test, its sensitivity and the nature of commodity which is being tested and quality/safety factors to be determined. In the case of non-official method, validation of the methods as per set norms is a must and their range of detection/quantification, L.O.D. /L.O.Q. limitations etc. must be established.

SOP as far as possible should be available for the test method and be available while performing any test to follow exactly the test method prescribed. No short cuts should be followed, and tests should not be done on a memory basis alone. The selection of methods is very important depending on the requirement of the test and the customer. It is also necessary for the estimation of uncertainty of measurement for each method.

External calibration of the equipment is to be done annually or depending upon its use. However, in case of any equipment being used very frequently, an internal calibration facility should be available and done regularly with a record.

In the case of required chemical standards in testing, whose purity can change the result should be certified reference material CRM with proper traceability. Standard solution/CRM Solution should be stored at the required temperature and conditions, and its strength should be checked regularly. Also, the Purity of the solvents, water being used, and other chemicals should be checked regularly.

In the case of microbiological analysis, standard culture must be available to establish the confirmation of the microbes. SWAB testing must be done for the inoculation room and media preparation room regularly to ensure that it is not contaminated. Special precautions should be taken for pipetting and ejecting the solution from the pipette. The solution should not be blown by air through the mouth.

All the apparatuses especially glass should be contamination-free and should be cleaned and rinsed thoroughly before use. No chemicals should be used after its expiry or otherwise if it looks like deteriorated or decomposed.

2.1.6 Subcontracting

Subcontracting or the use of subcontractors is understood to mean a situation where the laboratory allows an analysis to be performed by another laboratory and uses the result in the laboratory's test report. (NMKL, 2010)

The laboratory allows the work to be done by subcontractors, either due to unforeseen circumstances or as a planned subcontract. It should be ensured that the work is given to a competent subcontractor (e.g. a laboratory that is accredited for the service). In certain situations, it may be justifiable, appropriate and reasonable to use subcontracting as an alternative to own analytical work. This applies e.g.:

1. The laboratory lacks competence or capacity to perform the analysis in question, and the analysis is only a minor part of the whole task,
2. There is a clear indication of an isolated need for the analysis in question and it is therefore not expedient to bind either personnel or instrument resources to this analysis,
3. The subcontractor's competence and efficiency are superior to the laboratory's own.

A subcontract may be used as an exception, or as a permanent service. Laboratories that use subcontractors should be able to document that the subcontractor performs the work at the same level of quality as the laboratory would itself. The laboratory should, therefore, archive relevant information on how the subcontractor's competence has been investigated, and which requirements for quality the subcontractor satisfies. (NMKL, 2010)

2.1.7 Personnel

There should be enough numbers of the working staff, who should be qualified and trained (trainees should have trained for the expected work) and should have a clear job description. (WHO, 2011)

The Food Safety laboratories should have a set of procedures and training systems to provide staff members with technical competence. Competent employees have the responsibility to examine food, staff should have appropriate practical work experience.

On the other hand, staff training should include all methods and techniques related to food safety testing. At a minimum, each analyst should demonstrate competency through observation by management and verification using replicate and/or check samples. (International Accreditation Service, 2015).

The competency requirements for each function influence the results of laboratory activities which should be determined, including requirements for education, training, qualification, technical knowledge, experience, and skills. (ISO/IEC 17025:2017)

The laboratory should have a procedure(s) and retain records for selection, training, supervision, authorization, and monitoring competence of personnel. The management of the laboratory shall communicate to personnel their duties, responsibilities, and authorities. And authorize personnel to perform specific laboratory activities such as development, modification, verification and validation of methods; analysis of results, including statements of conformity or opinions and interpretations; and report, review, and authorization of results.

2.1.8 Equipment

FSL should be furnished with all items and elements for sampling preparation and performing analysis. It is necessary for the correct performance of testing. On the other hand, the frequency of calibration of equipment should be appropriate for operating the equipment to achieve the accuracy relevant to the method. A documented procedure for “handling, transport, storage and measuring equipment" is to prevent contamination or deterioration. While the main equipment should undergo regular maintenance and service. (International Accreditation Service, 2015)

The main equipment that need regular maintenance are refrigerators, freezers where samples and certified reference samples are stored, ovens, incubators, water baths, centrifuges, pH meters, balances, analytical instruments such as chromatographs and spectrometers.

FSL should have access to the equipment (including measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or

auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. (ISO/IEC 17025:2017)

Also, FSL should have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure the proper functioning and to prevent contamination or deterioration and verify the equipment that conforms to specified requirements before being placed or returned into service. The equipment used for measurement should be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

Measuring equipment shall be calibrated when the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or calibration of the equipment is required to establish the metrological traceability of the reported results. Establish a calibration program, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration. All equipment requiring calibration, or which has a defined period of validity shall be labeled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service and isolated to prevent its use. (ISO/IEC 17025:2017)

2.1.9 Facilities and Environmental Conditions

The facilities and environmental conditions should be suitable for the laboratory activities and should not adversely affect the validity of results. The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be determined.

The laboratory will monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results. Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include access to and use of areas affecting laboratory activities; prevention of contamination, interference or adverse influences on laboratory

activities; and effective separation between areas with incompatible laboratory activities. (ISO/IEC 17025:2017)

Adequate control of temperature, humidity and dust is important to staff comfort, instrumental performance and safe working (e.g. with flammable solvents). It is also important to perform properly optical instruments which often require stable temperature conditions. Electronic equipment may have prescribed operating ranges for environmental temperature and humidity. Computers may need to be protected from strong magnetic fields from other equipment; any staff or visitors with heart pacemakers must avoid such fields. Cooling water, either from mains supplies or localized refrigeration may be necessary for the proper functioning of some equipment. Test materials, reagents, standards may need to be stored under controlled conditions. Some substances are affected by sunlight or fluorescent lights and must be protected from it. Delicate balances and optical instruments may need to be protected from vibration (e.g. from blenders, shakers and centrifuges) or may even need stabilized supports. All these needs have to be identified and documented so that proper procedures for monitoring them and taking necessary action can be included in the quality assurance system.

Also, Records will be needed to show the samples which are received, stored, handled and analyzed under environmental conditions that will not adversely affect analyses; ensure the temperature, humidity and light controls are adequate in sensitive areas to protect samples, extracts from them, personnel and equipment; and the results of environmental sampling in laboratory areas are recorded; these should include records of air-flow rates across fume cupboard apertures. (Food Safety and Standards Authority of India, 2016)

As with any other aspect of the laboratory's activities, the responsibility for housekeeping activities must be clearly defined. Cleaning staff and laboratory staff should have clear instructions as to their respective duties in relation to: cleaning of floors, surfaces, equipment, refrigerators, freezers, fume cupboards, stores; controlling the contents of refrigerators, freezers, fume cupboards, controlled environment stores; checking the performance of air-conditioning and dust extraction equipment and fume-cupboards; and Pest control. (Food Safety and Standards Authority of India, 2016)

2.1.10 Sample Management

Sampling often begins with routine collections for surveillance purposes, food safety inspections, monitoring studies or as a response to a complaint. Collected samples may include investigative, documentary, emergency response, law enforcement, and research or convenience samples. The best practices in sample collection should reserve the essential characteristics of a valid, official sample include ensuring that the sample contains a representative portion of the lot, sampled in a manner that assures it is not changed in its physical, chemical or biological nature from the whole. Also, the sample should be collected, preserved and handled in a manner consistent with the intended testing. Also, any required sample reserve portions should be collected, and the sample should be accompanied by accurate records that legally establish its identity, responsible individuals and chain of custody. (The Partnership for Food Protection Laboratory Task Group, 2013).

The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test samples, including all provisions necessary to protect the integrity of the test and to protect the interests of the laboratory and the customer. Precautions should be taken to avoid deterioration, contamination, loss or damage to the samples during handling, transporting, storing/waiting, and preparation for testing. Handling instructions provided with the item shall be followed. (ISO/IEC 17025:2017)

The laboratory shall have a sampling plan and method when it carries out sampling of food products for subsequent testing. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing.

The tested specimen should be kept for an appropriate period as per the policy. Only authorized person(s) will discard the unused specimen and the specimen management procedure shall be documented. (Kusum, M. Silva, P. 2005)

2.1.11 Reporting the Results

The results shall be reviewed and authorized before release. The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report, and

include all the information agreed with the customer and necessary for the interpretation of the results and all the information required by the method used. All issued reports will be retained as technical-records.
Each report shall include at least the following information: the title, the name and the address of the laboratory, the location of performance of the analysis, unique identification, the name and contact information of the customer, identification of the method used, a description, unambiguous identification, and, when necessary, the condition of the sample, the date of receipt of the test sample(s), and the date of sampling(where this is critical to the validity and application of the results), the date(s) of performance of the analysis, the date of issue of the report, reference to the sampling plan and sampling method, a statement to the effect that the results relate only to the items tested, the results with units of measurement, deviations or exclusions from the method, identification of the person(s) authorizing the report, clear identification when results are from external providers. (ISO/IEC 17025:2017)

In addition, a disclaimer should be added to the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

2.1.12 Complaints

The laboratory shall have a documented process to receive, evaluate and make decisions on complaints. A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints. The process for handling complaints shall include at least the following elements and methods:

1. Description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
2. Tracking and recording complaints, including actions undertaken to resolve them;
3. Ensuring that any appropriate action is taken.

The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint and provide the complainant with progress reports and the outcome. The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question. Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant. (ISO/IEC 17025:2017)

2.2 Selected Previous Studies

Brereton and his colleagues (2006) showed some case studies from Africa. These case studies concerned with issues associated with the establishment of effective food safety monitoring laboratories in countries where there are significant resource gaps. The role of the private sector laboratories in these case studies illustrates the growing interface between public and private laboratories delivering services in support of national and international food safety standards.

While, Mwamakamba and his colleagues (2012) studied the components of a modern national food safety control system and examines efforts at strengthening national food safety control systems in the African Region. They concluded that these countries faced many challenges of their food control systems, they were “limited awareness about food safety; inadequate coordination between several government ministries; inadequate enabling policy and outdated legislations and regulations; insufficient and inadequate capacities for food safety; and inadequate resources for food safety”.

Gerhard Rimkus (2015) assessed three main food laboratories of the Agency on Standardization, Metrology, Certification, and Trade Inspection (Tajikstandart, TJT) under the Government of the Republic of Tajikistan to evaluate the capacity and capability of relevant food laboratories in Tajikistan to analyze premixes and fortified food, The assessment was based upon the data of a questionnaire with accompanying documents and the visits to the food laboratories. This assessment mainly focused on the laboratory accreditation and quality management, testing scope and sample capacity, instrumentation, facilities/building and training status of personnel. Besides the testing capability and capacity relating to fortified foods also the analysis of food quality and safety parameters was including in this assessment.

Since food is composed of thousands of different nutritive and nonnutritive compounds that embedded in a variety of different plant and animal matrices. No desirable biochemical compounds such as environmental contaminants, microbial and plant toxins and veterinary drugs are also present with their presence posing a danger to human health. In analytical food chemistry, the isolation, identification, and quantification of both desirable and undesirable compounds continue to pose immense challenges to food analysts. Methods and tests used to isolate, identify, and quantify must be precise, accurate, be increasing sensitive to satisfy the rigors of investigative and applicable science, have minimal interfering factors, use minimal hazardous chemicals, and produce minimal/no hazardous wastes.

At this contrast, Varghese and her colleagues (2016) were concerned with the analytical methods (chemical and microbiological) used to determine the presence, and to identity and quantity of all compounds of interest in a food. They argue that "it is impossible to address the quantitative and microbial analysis of all food components, since food analysts have a variety of available tests, but the test choice is primarily dependent on the goal of the analysis and the use of the final data. Many of the traditional analytical biochemical tests such as Kjeldahl digestion for protein determination are still regarded as the gold standard and are still used in many laboratories. While useful, traditional analytical methods are continually being challenged by technological and instrumental developments".

While Morse and his colleagues (2018) tried to achieve "an integrated approach of food safety and hygiene – meeting the sustainable development goals", where they applied their study in Malawi as an example of Sub-Saharan African countries, they concluded that "there is a significant threat to public health and market access due to uncoordinated, outdated or incomplete regulatory framework, poorly defined mandates, limited infrastructure, lack of equipment and skilled personnel, inadequate resources, and limited awareness and ability to comply with standards". This result improves that food safety and hygiene improvements must have a balance between market access gains and protection of public health".

On the other hand, Mwamakamba and his colleagues (2012) mentioned that modern food safety system must include "enabling food laws, policies, regulations and

standards; mechanisms for coordination; operational food inspection and laboratory services as well as national information, education and communication programs".

NACMCF (2009) concluded that "Choosing a laboratory requires careful consideration, because not all laboratories have the expertise to design challenge studies and the quality control procedures necessary to produce valid results that will be accepted by the regulatory authority or other reviewer. Laboratories may be certified by various organizations and state or federal agencies for various types of testing, e.g., water and waste water testing, ISO 17025, and Grade A dairy testing. However, these certifications do not necessarily qualify a laboratory to design and conduct microbiological challenge studies".

In India, Food Safety and Standard Authority (2016) introduced Guideline (Good Food Laboratory Practices GFLPs) specifies the general requirements for the competence to carry out systematic sampling of food samples, conduct chemical, microbiological tests and testing of packaging materials to ascertain the quality of food. It covers the tests performed using standard methods, non-standard methods, and laboratory-developed methods.

Mohammad Ayesh (2016) assessed (from a microbiology point of view) two Palestinian governmental food laboratories the first one was CPHL in Ramallah and the second was the CVL-food safety laboratory in Hebron. The assessment was based upon the data of onsite visits, document revision, and staff interviews to come out with recommendations aim to strengthen the capacities of mentioned laboratories and enhance their technical cooperation. The study aimed to assess and prepare recommendations towards the mandate of the laboratory, the ability of the laboratory to quantitatively increase testing plus recommendations on required measures to realize this potential increase.

In conclusion, most scholars and researchers investigated issues related to food safety systems elements in general including assessment of food safety laboratories services, within chosen samples among persons who worked at private/public laboratories, they applied different methodologies that were varied between questionnaires and interviews. The findings showed that these laboratories faced many difficulties and obstacles such as (financial support, qualified staff, updated and qualified tools and

equipment), so they used to test food safety with limited capacities. However, no previous studies have been undertaken to assess PFSL up to now. The current research focused on the assessment of the competence public and private PFSL, in addition to finding out the main procedures that control authorities used to test food safety and the relationship between food control authorities and PFSL.

CHAPTER THREE: MATERIALS & METHODS

The purpose of this chapter is to discuss the research procedures and techniques which are used in this research. It also presents the research approach, research strategy, data collection tools, data analysis, and data validation.

3.1 Methodology

This study aims at investigating PFSL capacities and the assessment according to the international accreditations and standards. Therefore, the purpose of this study is mainly exploratory and descriptive analysis. Both the questionnaire and the interviews have been used in this research.

Therefore, both quantitative and qualitative approaches were adopted. According to Johnson and Christensen (2008), a qualitative method is used to analyze social interactions; it's good for selected groups, where data analysis is used to identify patterns, and themes.

In order to achieve this part, two questionnaires (included open/closed questions) were prepared and distributed among the selected groups in order to find out the answers to the study questions.

1. The first questionnaire was developed for PFSL with eight main parts included (general information about laboratory) at the first part, while the remain included seven main fields that explained the assessment (Quality system, Methods of analysis, Laboratory equipment, Facilities/building, Human resources "Personnel", Sample management, and problems),

2. The second questionnaire was designed specially to interview three control authorities to know the main procedures used to test food safety, and the relationship between control authorities and PFSL.

The study utilized on-site questionnaire type and distributed among the managers and specialized employees in the PFSL for the easiness and guarantee of collecting the

distributed questionnaires. The response rate of on-site questionnaire was (100%), since the researcher got the approval to meet them directly from the managers of these laboratories.

3.2 Research Sample

The research investigated all the nine existing private and public PFSL (West Bank and Gaza Strip), by using a comprehensive methodology survey. While the second sample was related to the three control authorities (Ramallah).

3.2.1 PFSL

Recently, there are nine public and private working laboratories concerned with food safety tests in Palestine; the following table shows general information about these laboratories.

Table (3.1): list of public and private PFSL with general information.

#	Laboratory name	General information
1	**Central public health laboratory (CPHL) – Ramallah**	CPHL is a governmental laboratory affiliated to MOH in the west bank. CPHL is one of the important departments that carry out many tasks for diagnosis, scientific research and training in matters related to the health of the Palestinian citizen and the health of the environment. CPHL includes several sections: Samples Reception, Chemistry, Medicine, Microbiology, Immunology Infectious Diseases, Hormones and Enzymes, Molecular Biology, Quality, Energy and Radiation Protection, Research.
2	**Scientific center for food and drug analysis – Nablus**	Established in 1999, the Scientific Center has a single branch in Nablus. Provides inspection services for many local and imported food products, as well as inspecting water, medicines, detergents and toxins. The laboratory consists of two sections: section of Microbiological Testing and section of Chemical Testing. The center applies the quality procedures of ISO 17025 and is accredited PALAC. The main clients of the Center are government agencies, factories and individuals.
3	**Analysis, Poison Control and Calibration Center (APCC) / Al-Najah University – Nablus**	In 1999, the "Analysis, Poison Control and Calibration Center (APCC)" was established as one of Al-Najah National University specialized centers in the field of delivering services to the Palestinian community. APCC includes three units: Analysis and Calibration Unit (ACU), Poison Control and Drug Information Unit (PCDI), Al-Najah Biosciences Unit (NBU). The Analysis Unit is the first unit of (APCC), specialized in providing the comprehensive and integrated services in the fields of chemical, biological and advanced assays for several materials and products necessary for the Palestinian society. These include food, food additives, medicines, detergents, raw materials, pesticides, feed, water and air. In addition to the conformity testing extent of these materials to local and international standards. The Analysis Unit has the

#	Laboratory name	General information
		Palestinian Accreditation Certificate, which is certified by (PALAC).
4	**Testing Laboratories Center TLC – Birzeit University**	Testing Laboratories Center (TLC) was established in 1982 at Birzeit University as one of the community outreach centers offering services in the fields of quality control, scientific researches, technical field studies and training to support the Palestinian community and enhance their development activities. TLC includes following Units: Pharmaceutical Safety Unit, Food Safety Unit, Environmental Health and Water Unit, and Petroleum Products and Lubricating Oil Unit. TLC works in three main areas: Testing and quality control, Training Development Projects, and Supporting Scientific Research.
5	**Public Health Lab.-M.O.H – Gaza**	The Public Health Laboratory is a governmental laboratory affiliated to MOH in the Gaza Strip, and It consists of five units: Chemistry, Microbiology, Pharmacology, Toxicology, and Quality Control. The laboratory conducts microbiological, chemical and physical tests for food, water, detergents, chemicals and medicines. The examination of food safety in the local market and factories to ensure compliance with Palestinian food Specifications and Control of food borne diseases. Laboratory Customers are: MOH inspectors, Municipal inspectors, The Environmental Health Inspectors, MOA Inspectors, MONE Inspectors, the owners of food factories, and Researchers and students studying in universities.
6	**Qalqilia Municipality Laboratory – Qalqilia**	The laboratory is affiliated to the Health and Food Quality Department in Qalqilya Municipality to be the first food laboratory in the local authorities to serve the citizens in the city. Where food products will be inspected from various shops and establishments in order to maintain public health and improve the quality of performance, and health and periodic control on the quality of food produced and imported to the city in cooperation with the regulatory authorities. The municipality's laboratory also conducts health education programs for the community and schools.
7	**Veterinary Lab MOA – Gaza**	Veterinary Lab -MOA is a government veterinary laboratory affiliated to the Ministry of Agriculture in the Gaza Strip, and provides laboratory inspection services for products and raw materials of animal origin such as: Diagnosis of Salmonella in eggs and meats, and Diagnosis of Brucella.
8	**Food safety lab – central veterinary laboratory (CVL) – Hebron**	Central veterinary laboratory (CVL) is a government veterinary laboratory affiliated to MOA in the west bank. CVL is one of the main departments of the Palestinian veterinary services that perform tests for animal health and food (the safety and quality of meat and dairy products). CVL consists from two unit: Food safety unit and Animal health unit.
9	**Medicare Laboratory – Ramallah**	Medicare is a Palestinian company established in 1995 that has attracted the best competencies and expertise in the field of laboratory medicine in its various branches, currently consists of a network of laboratories distributed in many governorates of the country, and laboratory tests are subject to many internal and external quality control programs. The laboratory carries out many medical tests mainly in various branches in Palestine, and microbiological tests for food and water in one of the laboratory branches in Ramallah city only.

Source: Interviews with the laboratories' managers conducted from (1/1/2019 to 30/3/2019) by the researcher.

The first tool of the study was (questionnaire1) which consisted of eight main parts, where the first one introduced the sample characterization; the following table shows these results:

Table (3.2): Frequencies, Percentages of first sample (PFSL) characterizations.

Item	Category	Frequency	%
Location	West Bank	7	77.8
	Gaza Strip	2	22.2
Type of laboratory	Private	4	44.4
	Governmental	4	44.4
	Municipality	1	11.1
	Research Institute	-	-
Main Activities	Microbiological tests	1	11.1
	Chemical tests	-	-
	Microbiological and Chemical	4	44.4
	Microbiological, Chemical and other tests	4	44.4
Main Customers	Individuals and private sector	1	11.1
	Government agencies	2	22.2
	Both (public and private) sectors	6	66.7
Source of Laboratory Budget	governmental and NGOs	2	22.2
	governmental	3	33.3
	Private	4	44.4
Total		9	100.0%

3.2.2 Control authorities

The second tool of the study (questionnaire 2) was distributed to three inspectors who worked at the Palestinian authorities which were responsible of monitoring and testing food safety in Palestine (i.e., food factories, restaurants, bakeries, markets, and meat shops). The following table shows the characteristics of the second sample:

Table (3.3): the second research sample characterizations (Control Authorities).

Item	Category	No.
Location	West Bank	3
	Gaza Strip	-
Main Activities	Sampling only	-

Item	Category	No.
	Inspection / Control only	-
	Both	3
laboratories that are dealing with	- CPHL - Ramallah - APCC - Nablus - TLC – Birzeit - Scientific Center – Nablus alone	3
Total		3

As can be seen from the table above, it showed the following:

- **Location**: The control authorities' sample work at West Bank – Ramallah, since these authorities are centralized at West Bank, while the others reconsidered as branches, so the study implemented at these centers that represented the other branches.
- **Main activities:** All of **c**ontrol authorities had sampling and inspection / control activities, while there was no control authority that implement inspection or only sampling activities alone among the chosen sample.
- **Proposed laboratories** (laboratories that are dealing with): the findings showed that all the control authorities dealt with four laboratories (CPHL, APCC, TLC, Scientific Center).

3.3 Study Tools

To achieve the purpose of the study, the researcher used two questionnaires as the study tools that were distributed among the selected samples (see Appendices A and B), it also depended on the collected data that the researcher gained from his visits to PFSL, control authorities, accreditation body (PALAC), and Center of Quality in Medical Laboratories (EQAS).

3.4 Data Validity and Reliability

Validity and reliability are two tests that the researcher used to make sure that the research is reliable and valid in all possible ways.

3.4.1 The Validity of the Research Tool

Validity test showed what the tool (questionnaire) was supposed to measure, and how it will measure it (Ghosh and Majumdar, 2011). Hereby, our study tool (questionnaire 1)

had been taken and modified from (Rimkus, 2015) study tool, while (questionnaire 2) was designed and developed by the researcher.

To achieve the research validity, the following steps were implemented:

1. The proposed questionnaires delivered to four specialists' arbitrators to refine the research tools (structured, and semi-structured), some modifications were made in order to assure the research tool can achieve the research aims.
2. Two research methods were used in data collection; the first one was the quantitative method that was represented by the on-site questionnaire, while the other one is qualitative method that used face-to-face interviews with the study samples.

3.4.2 The Reliability of the Research Tool

According to Ghosh and Majumdar (2011), there are essential aspects in reliability which concerns with objectivity and consistency. In this research, the researcher checked reliability of the quantitative tool (questionnaire1) by checking consistency through Cronbach Alpha test, where the acceptable value should range between (0.70-0.95) (Tavakol and Dennick, 2011).

The following table shows these results:

Table (3.4): Cronbach Alpha test results for all parts and the all-in-all level of the questionnaire 1.

Part	Cronbach Alpha
Part One: Quality System	0.817
Part Two: Methods of analysis	0.925
Part Three: Laboratory equipment	0.883
Part Four: Facilities / Building	0.792
Part Five: Human resources	0.851
Part Six: Sample management	0.884
Part Seven: Managerial and Technical gaps (Existing Problems)	0.930
All-in-All	0.881

The findings of the previous table showed that there was a good reliability between statements of the all parts of the sample answers at the study tool (questionnaire1),

since the Cronbach Alpha score was (0.881) which means that there are a very good homogeneity between the respondents' answers.

3.5 Data Analysis

The submitted on-site questionnaires were entered into the SPSS database and analyzed. A descriptive and an inferential analysis were conducted. The descriptive analysis was applied to represent percentages of the respondents' answers, and then a discussion was written under each of the results. Also, conducting a SWOT analysis for PFSL.

3.6 Procedures

To achieve the purpose of the study, the following steps were carried out:

1. Gathering information to identify all the laboratories involved in food safety analysis and food control authorities.
2. Literature Review to collect and analyze available documents related to FSL**.**
3. Developing two questionnaires for PFSL and food control authorities.
4. Focus group to take their advices and consultations about the objectives of the study, and to evaluate the proposed study tool (questionnaire 1+2).
5. Visiting and distributing the tow questionnaire to nine PFSL and three control authorities to obtain in-depth information about laboratories from key persons, and to gather information about food control authorities work, activities related to the testing of food samples, and the relationship with PFSL.
6. Checking the validity and reliability of the research tools by checking consistency through Cronbach Alpha test.
7. Analyzing the results by using SPSS program.
8. identify strengths, weaknesses, opportunities, threats of PFSL (SWOT analysis),
9. Discussing the findings of the assessment with the supervisor.
10. Defining the desired future situation of FSL and Identifying capacity building needs to strengthen PFSL.
11. Determining options to strengthen PFSL based on the identified needs.

3.7 Timetable of Research

The following table shows the timetable of the research.

Table (3.5): Research timetable

Activities	2018				2019											
	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Literature review																
proposal Writing																
proposal submission																
Data collection																
Finalization of data collection																
Data analysis																
Thesis writing																
Thesis submission																
Thesis discussion session																

CHAPTER FOUR: RESULTS AND DISCUSSION

This chapter presents the results collected through the two questionnaires (PFSL questionnaire and control authority's questionnaire) and it introduces the discussion about these results, and finds out the answers to the research questions.

4.1 Results and Discussion

4.1.1 PFSL Tests and Available Equipment

Question one stated that: "What are the main tests and equipment available at PFSL that conduct food safety tests?"

The following table shows the results related to the main tests performed, and the main equipment available at PFSL.

Table (4.1): Main tests & available equipment at PFSL

#	Laboratory Name	Main Tests	Main Equipment
1	**Central Public Health Laboratory (CPHL)**	**Microbiological Tests**: which included (Listeria Monocytogenes, Vibrio Cholera In Food Products., Total Aerobic Count, Total Coliforms, Fecal Coliforms, Staphylococcus Aureus, Salmonella, Yeast, Mold, Listeria Monocytogenes, Bacillus Cereus, Vibrio Parahaemolyticus, Lactobacillus, Clostridium Perfringens, Campylobacter, E.Sakazaki). **Chemical Tests:** which included (Minerals, Preservatives, Sweeteners, Peroxide, Aflatoxins, Vitamins, Protein, Acidity, Ash, Fat, Moisture, Peroxide Value, Pesticide, HMF, PH, Brix, Carbohydrates, and Antibiotics).	(HPLC, GC, Water distillatory, pH meter, hoods, Pulse filed gel electrophoresis, Incubator, Centrifuge, Vortex, Spectrophotometer U-V visible, Spectrophotometer UV-VISI, turbidity meter, Flame photometer, Atomic absorption spectroscopy, E.C meter, Steam sterilizer, Incubators, Ultraviolet electric unit, Microscope fluorescence, colony counter, viscosity and density meter, centrifuge, shakers, water purification system).
2	**Scientific Center for Food and Drug Analysis**	**Microbiological Tests**: which included: Total Coliforms, Yeast And Molds, Fecal Coliforms, Total Aerobic Count, Staphylococcus Aureus, Listeria Monocytogenes, Salmonella, Legionella, Pseudomonas, Escherichia Coli. **Chemical Tests:** which included: Food Colors, Sucrose, Antioxidants, Brix, So2,	(HPLC, UV/VIS, GLC, integrator, Nano color, pH meter, GC/MS, vortex, centrifuge, UPS, fat analyzer, protein control, block digester, CO_2 incubator, laminar flow, furnace, refractometer, Brixstix, TDS tester, autoclave, VISCO tester, hood)

#	Laboratory Name	Main Tests	Main Equipment
		Preservatives, Acids, Caffeine, Minerals And Heavy Metals, Protein, Fat, Starch, Moisture, Salt, Nitrite, Flavor Enhancers, Bulking Agents, Acids Regulators, Benzoic And Sorbic Acids, Acidity, TDS, Sweeteners, PH, Peroxide, Ash, Aflatoxins, Pesticides, Vitamins, Specific Gravity, HMF, Veterinary Drugs And Hormones, Delta K, Halogenated Compounds .	
3	**Analysis, Poison Control and Calibration C enter (APCC)**	**Microbiological Tests**: which included: Total coliforms, Yeast and molds, Fecal coliforms, Total aerobic count, staphylococcus aureus, listeria monocytogenes, salmonella, Legionella, Pseudomonas, Escherichia coli, clostridium perfringens, clostridium botulinum, campylobacter, lactobacillus. **Chemical Tests:** which included: (Brix, PH, Fiber, Acidity, Ash, Nitrogen Content, Peroxide, Invert Sugar, Sucrose, HMF, Moisture, Salt, Monosodium Glutamate, Starch, Nitrites, Fat, Phosphates, Protein, Caffeine, Benzoate, Sweeteners, Total Organic Matter, Insoluble Matter, Aflatoxins, Minerals, Preservatives, Colors, Acids, Antioxidant, Vitamin C, Refractive Index, Saponification Number, Iodine Number, Unsaponification Number, Delta K)	(Gas chromatography, mass spectrometer, Karl fisher, HPLC, Spectrophotometer, Elemental analyzer, Laminar flow, Fat extractors, Autoclave, FTIR, Fume hood, Freeze dryer, Dissolution system, Rotary evaporator, Viscometer, Coductometer, Moisture balance, Digester, Refractometer, Polar meter, Low pressure liquid, chromatography, ICP-MS, Incubators, Aflatoxins test, Uv visible, Flame photometer, Furnace).
4	**Testing Laboratories Center TLC**	**Microbiological Tests**: which included: (Total Coliforms, E-coli, E-Coli 0157, Streptococcus faecalis, Enterococcus Faecalis, Yeast and Molds, Total Aerobic Count, Staphylococcus aureus, Enterobacter sakazii, Pseudomonas aeruginosa, clostridium botulinum, Clostridium perfringens, Lactobacillus, Vibrio, Bacillus Cereus, Salmonella, Listeria monocytogenes. **Chemical Tests:** which included: (Pesticides, Minerals and Heavy Metals, Preservatives, Food Colors, Sugars (Glucose, fructose, Sucrose), Sweeteners, Protein, Fat, Total Solids, Starch, Salt, Moisture, Carbohydrates, Vitamins, Fiber, Ash Content, Free Fatty Acid, Peroxide, Vitamins, Aflatoxin's, HMF, Brix, delta K).	(ICP, HPLC, HPLC MS, GC, GC/ MS, Direct Mercury Analyzer, Spectrophotometer, Ion Chromatogram , Capillary Ion Analyzer CIA, Incubators, Autoclaves, Microscope, Stomacher, pH meter, hoods, colony counter, Rota vapor, Bomb Calorimeter, Refractometer, Infra-red balance, UV/VIS, fat extractor, Kjeldahl, Ovens, Fourier transform infrared spectroscopy FTIR, Thermogravimetric analyzer TGA, hoods, viscosity and density meter, centrifuge, shakers, water purification system).
5	**Public Health Lab.-M.O.H - Gaza**	**Microbiological Tests**: which included: (Aerobic plate count, staphylococcus aureus, fecal coliform, total coliform, E. coli, streptococcus fecalis, salmonella, shigella, campylobacter, Yersinia, Vibrio cholera, listeria monocytogenes, bacillus cereus,	(HPLC, Gerber centrifuge unheated, Water distillatory, PH meter, hoods, Pulse filed gel electrophoresis, Incubator, Centrifuge, Vortex, Spectrophotometer U-V visible,

#	Laboratory Name	Main Tests	Main Equipment
		clostridium perfringens, mold &yeast, helminthes protozoa, animal parasites, acidic bacteria, clostridium botulinum). **Chemical Tests**: which included: (Moisture, ash, acidity, peroxide, saponification number, iodine number, pH, refractive index, TSS, salt, starch, inverted sugar, sodium nitrite, SO_2, fat content, preservative, sugar, gluten, HMF, Titanium dioxide, alcoholic test, protein, benzoic and sorbic acids, sweeteners, caffeine, TVN, H_2O_2, Turbidity, Electrical conductivity, Total dissolved solid, Nitrite, Ammonia, Total alkalinity, minerals and heavy metals).	Spectrophotometer UV-VISI, turbidity meter, Flame photometer, Atomic absorption spectroscopy, E.C meter, Steam sterilizer, Incubators, Ultraviolet electric unit, Microscope fluorescence, Counter colony).
6	**Qalqilia Municipality Laboratory**	**Microbiological Tests** which included: (Total Aerobic Count, Total Coliforms, Fecal Coliform, E- Coli, Staphylococcus Aureus, Salmonella, Clostridium, Bacillus Cereus, Yeast and Molds, Hygiene's, Swabbing Test, Brucella). **Chemical Tests:** which included: (Antibiotic Sensitivity Test, PH,, Salinity, TDS, EC, Nitrite, Nitrate, Flour, Chloride, Sulfur, Phosphate For Water, and Milk Composition).	(Incubators, Laminar air flow, Autoclave, Colony counter, Stomacher, Mass balances, Dehydrators (silica gel), Filtration system, Water distiller, Milk analyzer, PH meter, Spectrophotometer, COD , BOD meter, Microscope, Turbidity meter, Conductivity meter).
7	**Veterinary Lab MOA - Gaza**	**Microbiological Tests**: which included: (Diagnosis of Salmonella in eggs and meats, Diagnosis of Brucella).	(Incubator, Autoclave, Mass balance, Microscope, Thermometer, Hot plate, Fume hood, Water bath, Desiccator, Distiller, Colony counter, PH meter, Stomacher).
8	**Food safety lab – central veterinary laboratory (CVL)**	**Microbiological Tests**: which included: (Salmonella). **Chemical Tests:** which included: (Somatic cells in milk, Antibiotic residue in meet, Antibiotic residue in milk, Helminths count in fish).	(Incubators, Masticator machines, Deep freezer, Water bath, Vortex mixer, Microscope, Negative pressure hood, water distiller, Colony counter, Autoclaves, Hot plates, PCR, Electrophoreses unit, HPLC, Test tube incubators).
9	**Medicare Laboratory**	**Microbiological Tests**: which included: (Total coliforms, Yeast and molds, Fecal coliforms, Total aerobic count, staphylococcus aureus, listeria monocytogenes, salmonella, Legionella, Pseudomonas, Escherichia coli).	(Incubator, Autoclave, Mass balance, Microscope, Hot plate, Fume hood, Water bath, Desiccator, Distiller, Colony counter, PH meter, stomacher).

Source: Interviews with the laboratories' quality managers conducted from 1/1/2019 to 30/3/2019 by the researcher.

The findings showed that there were some differences between PFSL at their applied tests and the available equipment they had. We can recognize that most of PFSL implement most of the microbiological, chemical and physical food safety tests, where the most frequent ones were as follows (microbiological tests: E-coli, TPC, FC, TC, Listeria, Salmonella and staphylococcus; and Chemical tests: Moisture content, Brix, Acidity, Fat content, Protein, pH, Preservatives, HMF, Salt and Acids).

On the other hand, five of PFSL had the main equipment to achieve the necessary microbiological, chemical, and physical tests, we also noticed that just the accredited PFSL had the main equipment necessary to achieve the chemical test, such as HPLC, GC, GC/MS, ICP, Spectrophotometer, UV/Vis., and Refractometer). While the other PFSL mainly concerned with microbiological tests.

4.1.2 The Accreditation of PFSL

Question two stated that: "What are the local or international accredited food safety laboratories, and what are the accredited food safety tests at these laboratories?"

The following table's show Frequencies and percentages were found for PFSL answers to the questions that discussed the accreditation of PFSL.

Table (4.2): Frequencies and percentages of answers to question (Is the laboratory accredited according to ISO 17025? If yes, since when? And what is the name of the accreditation body?)

Category	Yes		No	
	Freq.	**%**	**Freq.**	**%**
B1. Is the laboratory accredited according to ISO 17025?	5	55.6	4	44.4
B2. If yes, since when?	**Freq.**			**%**
1. Before the year 2000	3			60.0
2. Between the years 2000-2010	2			40.0
3. After the year 2010	-			-

As can be seen from the table above, the findings showed the following:

- More than half of the participants said that their laboratory was accredited according to ISO 17025 with (55.6%) mean, while the rest (44.4%) of the participants said that they were not accredited.

- About (60.0%) of laboratories said that they had been accredited before the year 2000, and (40.0%) of them said that they had been accredited between the years (2000-2010).
- All the accredited PFSL got their accreditation from national accreditation body (the Palestinian Accreditation PALAC).

The accredited PFSL had (ISO 17025) accreditation issued from local accreditation body (PALAC), where there is no international accreditation body exists in Palestine, while the rest of them, mostly, used most principles of international standard (i.e., ISO 17025).

To see an example of a Palestinian accreditation certificate for PFSL refer to appendix (C).

Table (4.3): list of accredited tests in an accredited PFSL

Laboratory Name	Accredited Tests	Type of Food
CPHL	Total Plate Count, Total coliform, Fecal coliform, E. coli, Salmonella, Shigella, Listeria spp., Staphylococcus aureus, Yeast and mold, Bacillus cereus, Clostridium perfringens, Lactobacillus, Yersinia, Campylobacter, Enterobacteriaceae. pH, Benzoic and Sorbic Acid Content and their salts, Fat Content.	General food
	pH, acidity, HMF, ash.	Honey
	Nitrites in curd meat	Meat product
	Fat, acidity, phosphates, total solid of milk, pH, fat, benzoic and sorbic acid.	Dairy products
	Iodine content, moisture, insoluble matter in water.	Salt
	Brix value	Beverages
Scientific center for food and drug analysis	Total Plate Count, Total Coliform, Fecal Coliform, Yeast and mold. pH, Benzoic and Sorbic Acid Content in food, Salt (Nacl), Aflatoxin.	General food
	Peroxide value, fatty acids profile.	Fat and oil
	Ash	Cereal products
	Brix value	Beverages
APCC	Total plate count, total coliform, E-coli, salmonella, listeria spp, staphylococcus aureus, yeast and mold. Brix value, pH, total dietary fiber.	General food
	Acidity	Fruits
	Ash of flour, nitrogen in flour, nitrogen in cereal products.	Flour and cereal products
	Acid value of butter fat, peroxide value of oils and fats.	Fat and oil
	Invert sugar, sucrose, HMF, moisture.	Honey
	Fat in milk, acidity of milk, phosphatase, protein in milk, fat in cheese, titanium in cheese.	Dairy products

Laboratory Name	Accredited Tests	Type of Food
	Benzoate, caffeine and saccharine in soda beverages.	Beverages
TLC	Total plate count, E-coli, salmonella, listeria spp, staphylococcus aureus, campylobacter. Phosphorus, total dietary fiber, cholesterol.	General food
	Specific Gravity, Acidity of fats and oil, Peroxide Value of Oils & Fats, Index of Refraction, Sterol, Saponification Value, Iodine value.	Fat and oil
	HMF, moisture.	Honey
	Nitrites in Cured Meat Protein in Crude Meat Starch in meat product.	Meat products
	Fat in dried milk, Phosphatase, benzoic and sorbic acid.	Dairy products
	Pesticides	Fruits and vegetables

It has been found that most necessary microbiological tests and some chemical tests accredited at the accredited PFSL. Even though, there are some necessary chemical tests not accredited at PFSL but should be accredited for food safety tests; such as (minerals and heavy metals). Despite the importance of accreditation for microbiological food safety tests, it was found that some of PFSL do not have accreditation for some microbiological tests such as (Total coliform, Yeast and Molds, and Listeria).

4.1.3 Implementation of Quality System Procedures

Question three stated that "Do PFSL implement quality system procedures effectively?"

The following table shows Frequencies and percentages were found for PFSL answers of the third question of the research that discussed the implementation of quality system procedures in PFSL.

Table (4.4): Frequencies and percentages of PFSL answers about the questions related to (the implementation of quality system procedures)

Category	Yes		No	
	Freq.	%	Freq.	%
B3. Is the laboratory working according to GLP?	-	-	9	100.0
B4. Is a Quality manager/Quality team in place?	7	77.8	2	22.2
B5. Is a Quality Manual present?	7	77.8	2	22.2
B6. Are internal audits organized on a regular basis?	6	66.7	3	33.3
B7. Have the laboratory participated in national or international inter-laboratory/ proficiency tests?	6	66.7	3	33.3
B8. Is there a process for handling complaints?	7	77.8	2	22.2

As can be seen from the table above, the findings showed the following:

- All PFSL never worked according to (Good Laboratory Practice: GLP) effectively, which presented (100.0%) of PFSL answers.
- Most of PFSL had a quality manager and/or quality team in place, with (77.8%) of agreement, while the rest (22.2%) said that the quality manager and/or the quality team were not in place all the time.
- Most of PFSL had a quality manual with (77.8%) of agreement, while (22.2%) said that the quality manual was not presented in the laboratory.
- Two-thirds of PFSL perform internal audits on a regular basis with (66.7%) of agreement, while there were (33.3%) of the participants said that the internal audits were not organized at their laboratories.
- More than half of PFSL had participated in national or international inter-laboratory proficiency tests with (66.7%) of agreement, while (33.3%) of them had not participated. Some PFSL that had started their participation between the years (2000-2010), while the other half of them had started their participation (after the year 2010). On the other hand, most of PFSL had participated with national provider EQAS, while the other laboratories had participated by other international providers such as: (GEMS, FAPAZ, APLAC, FMD and USGS). It also found that the most proficiency tests that the PFSL participated in were Microbiology tests such as: (salmonella, total coliform, fecal coliform), while some of PFSL participated in tests such as: (some tests for water, Peroxide and Acidity of oil, Cadmium in rice powder, zinc and iron in milk and flour wheat, Avian Influenza, and Brucella).
- Most PFSL had a specified process for handling complaints with (77.8%) of agreement, while the rest (22.2%) had not a ready process for handling complaints. PFSL that had a ready process for complaints by receive it, then fill the complaint in the (complaint form), then introduced to the responsible authorities or management to investigate and take the corrective action (such as re-test the sample), and carry out the corrective action, then document the final results in the same form.

The accredited PFSL implemented the quality system procedures as a requirement for accreditation, while some of the unaccredited PFSL applied some of these procedures. Moreover, all PFSL did not work according to GLP.

4.1.4 Practices Related to Methods of Analysis

Question four stated that: "What are the main methods and procedures applied at PFSL related to analysis?"

The following table shows Frequencies and percentages were found for PFSL answers of the fourth question of the research that discussed the implementation of procedures and methods related to analysis.

Table (4.5): Frequencies and percentages of PFSL answers about the questions related to (Methods of Analysis)

Category	Yes		No	
	Freq.	%	Freq.	%
C1. Are there SOPs for all analytical methods?	5	55.6	4	44.4
C2. Are analyses sub-contracted? If yes, please list the sub-contracted laboratories and the criteria to choose them for sub-contracted analyses	-	-	9	100.0
C3. Is there coordination with local laboratories?	4	44.4	5	55.6
C4. Are certified reference materials (CRMs) used?	7	77.8	2	22.2
C5. Are there available high purity and/or de-ionized water in the laboratory?	9	100.0	-	-
C6. Has the laboratory access to relevant literature (e.g. AOAC, ISO, EPA methods, scientific journals) and/or electronic databases?	1	11.1	8	88.9
C7. Insufficient of materials	8	88.9	1	11.1
C8. The inability to perform some tests necessary for food safety	7	77.8	2	22.2

As can be seen from the table above, the findings showed the following:

- About (55.6%) of PFSLs' answers said that there were "Standard Operating Procedures (SOPs)" for all analytical methods at their laboratories, while the other (44.4%) said that they did not have the SOPs at their laboratories, which reflected the same percentage of the accredited PFSL, because SOPs was considered as one of the accreditation requirements.
- All PFSL are used to repeat the non-compliant resulted, either by the same person or by another one with (100.0%) of agreement.

- All PFSL agreed that the analyses were not sub-contracted at their laboratories with (100.0%) of agreement.
- About (55.6%) of PFSL had no coordination with local laboratories, while (44.4%) of them used to coordinate between each other's.
- Most of PFSL used certified reference materials (CRMs) in their laboratories with (77.8%) mean, while (22.2%) had not used CRMs in their laboratories. Some of the PFSL mentioned that they used CRMs for fatty acid test, vitamins and preservatives.
- All PFSL used to process high purity and/or de-ionized water in their laboratories with (100.0%),
- Most of PFSL had no access to relevant literature (e.g. AOAC, ISO, EPA methods, scientific journals) and or electronic database with (88.9%) of disagreement, while the rest (11.1%) said that they had an access to relevant literature and or electronic database (NCBI journal),
- Most PFSL faced lack of materials with (88.9%), while only (11.1%) mentioned that they did not face lacking of materials, on the other hand, the most reasons of this problem related to the occupation / siege which caused limitation of materials with (55.6%), while there were (11.1%) mentioned that limitation of budget or complexity of procedures were one of the reasons that caused the lack of materials with (11.1%) for both causes.
- Most of PFSL were unable to perform some tests such as (heavy metals, minerals and pesticide residuals) that were necessary for food safety with (77.8%), while (22.2%) had not mentioned any problem. On the other hand, the main reason that made PFSL unable to perform certain tests for food safety related to (limitation of materials, expensive tests, occupation, lack of equipment, limited budget, and no trained crew).

4.1.5 Main Managerial Capacity Gaps

Question five stated that: "What are the main managerial capacity gaps in PFSL?"

The following table shows Frequencies and percentages were found for the respondents' answers of the fifth question of the research that discussed the main managerial capacity gaps in PFSL.

Table (4.6): Frequencies and percentages of the sample answers about the questions related to (the main managerial capacity gaps)

Category	Yes		No	
	Freq.	**%**	**Freq.**	**%**
D1. Insufficient lab staff	7	77.8	2	22.2
D2. Insufficient training of lab staff	5	55.6	4	44.4
D3. Is there an annual internal and external training program for the staff?	5	55.6	4	44.4
D4. Is a procedure in place to train new employees on analytical methods?	8	88.9	1	11.1

As can be seen from the table above, the findings showed the following:

- Most of PFSL suffered from lacking of lab staff with (77.8%), while (22.2%) had not faced this difficulty, it is also found that PFSL mentioned that the most causes were related to the complexity of recruitment procedures, which came with (28.6%), followed by low budget with (14.3%). It has found that (55.6%) of the PFSL had less than (10) employees.
- More than half of PFSL faced lack of training of lab staff with (55.6%), while the other (44.4%) of them had not face these problem, it is also found that (20.0%) of these laboratories mentioned that the crew participate at a training session when it was obtained from a third party only.
- About (55.6%) of PFSL had an annual (internal and external) training program for the working staff, while the other (44.4%) did not have any training programs for their staff,
- About (88.9%) of PFSL had at their future strategic procedure an item to train new employees on analytical methods, while the rest (11.1%) had not any training plans in the future.

So, most of PFSL suffered from insufficient lab stuff and insufficient training for them, even they received the necessary internal training, while the other training courses achieved externally when the fund is available. Since training is a necessity, PFSL put in its plans to train their employees (internally and externally).

4.1.6 The Main Technical Capacity Gaps

Question five stated that: "What are the main technical capacity (laboratory equipment, facilities/building, sample management) gaps in PFSL?"

Frequencies and percentages were found for PFSL answers of the fifth question of the questionnaire that discussed the main technical capacity gaps in PFSL. The following tables show these results.

Laboratory equipment

Table (4.7): Frequencies and percentages of the sample answers at the main technical capacity (laboratory equipment) gaps in PFSL.

Category	Yes		No	
	Freq.	%	Freq.	%
E1. Is there an inventory of all equipment available?	2	22.2	7	77.8
E2. Difficulties in maintenance operations	5	55.6	4	44.4
E3. Do you have maintenance procedures (internally / externally)?	9	100.0	-	-
E4. Do you have calibration procedures?	9	100.0	-	-

As can be seen from the table above, the findings showed that:

- Most of PFSL did not have an available inventory of all equipment, since (77.8%) of them said that there was no inventory available of all equipment, while (22.2%) said that they had it,
- More than half of PFSL faced some difficulties in maintenance operations with (55.6%), while (44.4%) of them had not mentioned any difficulties, where these difficulties concentrated into two categories (limited budget, complexity at managerial procedures, arbitrary occupation practices),
- PFSL used to maintain lab equipment either internally if there is an ability to perform, according to the approved maintenance procedures at the lab, or externally from (the manufacturing company or a third party).
- All PFSL had internal and external calibration procedures.

Most of PFSL faced some difficulties while maintaining their equipment (limited budget, complexity at managerial procedures and arbitrary occupation practices), and

most of them either achieve maintenance procedures internally (if maintenance unit exists or available expert), or externally, but mostly they perform the maintenance if needed. And most of them calibrated (mass balances, thermometers) externally at metrological firms, while the rest equipment calibrated internally upon the availability of reference materials.

Facilities / Building

Table (4.8): Frequencies and percentages of the sample answers at the main technical capacity (facilities/building) gaps in PFSL.

Category	Yes		No	
	Freq.	%	Freq.	%
F1. Does power back up exist? (Uninterruptible power supply-UPS and/or generator?	8	88.9	1	11.1
F2. Are air conditioning systems available?	9	100.0	-	-
F3. Are enough separate storage rooms available for chemicals, samples and disposal?	5	55.6	4	44.4
F4. Are enough fume hoods available?	7	77.8	2	22.2
F5. Are enough refrigerators and freezers available for the storage of chemicals / samples?	7	77.8	2	22.2
F6. Is a centralized (external) gas supply?	3	33.3	6	66.7
F7. Is there a cleaning schedule for the laboratory?	6	66.7	3	33.3
F8. Insufficient equipment	5	55.6	4	44.4
F9. Power cuts	4	44.4	5	55.6
F10. Water cuts	1	11.1	8	88.9
F11. Insufficient space	7	77.8	2	22.2

As can be seen from the above table, the findings showed that:

- Most of PFSL had an existing power back-up, with (88.9%) of agreement, where (3) laboratories had their own generators,
- Only one laboratory had USP, and (4) of them had both (USP and generator),
- All PFSL had air-conditioning system with (100.0%) of agreement,
- More than half of PFSL had enough separate storage rooms (available for chemicals, samples and disposal) with (55.6%), while (44.4%) of them did not have,
- Most of PFSL had enough fume hoods available in their laboratories with (77.8%) of agreement, while (22.2%) did not have,

- About (77.8%) of PFSL had enough refrigerators and freezers available for the storage of chemicals and samples with (77.8%), while (22.2%) of them did not have,
- Some of PFSL was provided with a centralized and external gas supply with (33.3%), while (66.7%) did not have a centralized gas supply,
- Two-third of PFSL had a cleaning schedule for laboratory with (66.7%), while (33.3%) did not have, since they clean the laboratory when needed,
- About (55.6%) of PFSL faced lack of equipment, while (44.4%) did not,
- Less than half of PFSL suffered from power cuts with (44.4%), while the rest did not face this problem with (55.6%).
- Only (11.1%) of the PFSL faced water cuts, where they mentioned that there was a technical problem (e.g. broken pipeline in the water net),
- Most of the PFSL suffered from insufficient laboratory space with (77.8%), since PFSL differ in the existing space (area), where (44.4%) of them had less than 250 m^2, while (33.3%) of them had an area between (250-500 m^2), and (22.2%) mentioned that they had more than (500 m^2) area.

So, PFSL provided with needed facilities (power back-up, air-conditioning, refrigerators, fume hoods), but they were in need of more equipment since they faced financial deficit (budget is low), and they suffered from power cuts because of Poor building insulation cause power cuts, Israeli siege and Israeli occupational operations, adding to that there were insufficient areas to add new sections.

Sample Management

Table (4.9): Frequencies and percentages of the sample answers to the statement (Total number of food samples analyzed per a year (2018)

G1. Total number of food samples analyzed per annum (2018)	Freq.	%
Less than 1000 sample	3	33.3
1000-5000 samples	4	44.4
More than 5000 sample	2	22.2

The findings of the table above showed that (44.4%) of PFSL analyzed between (1000-5000) sample through the previous year 2018, while (33.3%) of them had analyzed less

than 1000 sample, on the other hand, (22.2%) of PFSL had analyzed more than 5000 sample through the last year.

So, the number of tested samples depended on lab capacity (area, equipment, No. of laboratory staff, accreditation, and TAT) as internal factors, while there were external factors, such as (competition, price, location) that affected number of tested samples.

Table (4.10): Frequencies and percentages of the sample answers about (the sample management at PFSL).

Category	Yes		No	
	Freq.	%	Freq.	%
G2. Is the laboratory involved in sampling?	5	55.6	4	44.4
G3. Does your laboratory perform traceability of samples assured from reception to the reporting?	9	100.0	-	-
G4. Dose the laboratory has an electronic LIMS (Laboratory Information Management System)?	3	33.3	6	66.7
G5. Are certificates/reports issued and archived for each sample**?**	9	100.0	-	-
G6. Is there a target for the turnaround time (TAT) for each test? Note: (TAT: time between reception of sample and reporting the results)	2	22.2	7	77.8
G7. Do you keep stand by samples from each tested samples?	9	100.0	-	-

As can be seen from the above table, the findings showed that:

- More than half of PFSL introduced sampling service with (55.6%) and they had (procedures / instructions / SOPs) for sampling, while the other (44.4%) of them did not introduce sampling service at all,
- All of PFSL performed traceability of samples (assured from reception to the reporting), since of them used to give the sample an internal code while registering its information and requested test (electronically / manually), then send the sample to the appropriate section, then preparing sample for analysis, applying the test, and finally write the results at the (Certificate)
- About (66.7%) of PFSL used to trace the received samples personally, while the other (33.3%) applied their own electronic tracking system (LIMS),
- All PFSL used to issue certificates/reports for sample with (100.0%) of acceptance, and archived them either soft or hardcopy till 3-5 years,
- About (77.8%) of PFSL had no target for the turnaround time for each test, while (22.2%) of them had it,

- All PFSL used to keep stand by samples for each tested sample for specific time according to the product characteristics, where this sample may be used for retesting.

Based on the importance of sampling to ensure that the sample has been taken in an appropriate manner and conditions, it has been found that nearly half of PFSL introduced this service, while the rest depend on qualified inspectors from control authorities. While all of them performed traceability (personally/LIMS), where they used to give each sample an internal code to go on analysis. On the other hand, all PFSL issued and archived reports/certificates for each tested sample, which controlled manipulation. On the other hand, most of PFSL did not determine turnaround time for each test which leads to a fussy situation and causes disruption of customers' work. And they used to keep stand by samples for each tested one if there is a need for it.

4.1.7 Control Authorities

Question six stated that: "What are the main procedures that control authorities used to test food safety? And what are the relationship between control authorities and food safety laboratories?"

To answer this question, frequencies and percentages where used to analyze the samples' answer, the following tables show these results:

There are three control authorities that monitor on the establishments of food in Palestine; the following table shows the names and main activities of them.

Table (4.11): List of control authorities in Palestine and main activities.

Control Authority Name	Activities
Environmental Health Department - Palestinian Ministry of Health (MOH)	- Preserving the environment, and safety of food products. - Routine testing of water and food. - Monitoring of health hazards (landfills, solid and liquid wastes, medical wastes and wastewater). - Application of sanitary conditions for the licensing of trades and industries. - Combating insects and rodents to maintain the health of individuals. - Issuing licenses for trades and industries. - Expressing opinions on licensing factories. - Issuing food import certificates. - Participate in joint committees such as the Market Regulatory Commission and the

Control Authority Name	Activities
	Public Health and Safety Committee.
Consumer Protection Department – Palestinian Ministry of National Economy (MONE)	- Regulating and controlling markets and taking the necessary measures to protect the consumer and combat commercial fraud. It conducts supervisory tours on the warehouses to check the safety of the supply of products, in terms of their quality and suitability for human consumption, and control violations in accordance with the Consumer Protection Law. - Conducting periodic and unannounced visits to commercial establishments and importers and drawing samples of products for laboratory testing to ensure compliance with Palestinian standards and technical regulations. - Inspect the product label and make sure that there are no Israeli settlement products. - Spreading consumer awareness in Palestine. - Receiving, verifying and following up complaints from different types of consumers. - Cooperate with all relevant institutions to ensure the implementation of consumer protection laws. - Follow-up commitment to put the price tag on goods offered in shops.
Palestinian Standards Institution (PSI)	- Prepare and adopt Palestinian standards for products, and services; review, amend, replace and publish them. - Grant conformity marks and compliance certificates and - Provide inspection and testing services. - Establish a national system of metrology, unify the tools and methods of measurement, and provide calibration services. - Approve labels for products. - Cooperate with local and scientific institutions to achieve the objectives of the Institute and fulfill its duties and authorities. - Provide support and encourage research and development for testing laboratories recognized in the areas of standards and metrology. - Enter into agreements with Arab, regional and international institutions for mutual recognition of conformity marks and certificates and cooperate with them in the areas of quality infrastructure. - Respond to inquiries related to standards, technical regulations, and metrology and conformity assessment. - Provide training services for employees of the private and public sectors.

Source: Interviews with the control authorities' managers conducted from 1/8/2019 to 30/8/2019) by the researcher.

The findings of main activities of control authorities showed that most of them had the following activities:

- Monitoring food establishments (markets, restaurants, hospitals, and manufacturing food industry, bakeries, meat shops),
- Sampling and Testing local and imported food products in Palestinian market,

- Coordinating with Public Prosecution for cases related to Non-conforming food.

The control activities were distributed among all control authorities, and there is no official unified body to make any coordination between them.

Table (4.12): Frequencies and percentages of the sample answers toward (food safety testing procedures at control authorities)

Category	Yes		No	
	Freq.	%	Freq.	%
H1. Is there any food safety laboratory belonged to your authority?	1	33.3	2	66.7
H2. Do you have a plan for food sampling?	3	100.0	-	-
H3. Is there procedure (SOP) for sampling and transportation to laboratories? If yes, please describe.	3	100.0	-	-
H4. Do you have an official procedure for handling non-conforming samples? If yes, please explain.	3	100.0	-	-
H5. Do you keep records about failed samples (negative results) for future analysis and improvement? If yes, explain the type of analysis	3	100.0	-	-
H6. Had you ever requested food tests that are not accredited by PALAC? If Yes, explain why?	3	100.0	-	-
H7. Do you deal with complaints about the results of the tested samples? If yes, please explain.	1	33.3	2	66.7
H8. Is there agreement with Palestinian food safety laboratories about information communication?	3	100.0	-	-

The findings of the table above showed that:

- About (66.7%) of control authorities did not have any PFSL that belonged to, while (33.3%) of them had a belonged laboratory such as CPHL,
- All control authorities had their own plan for food sampling, where samples could be taken periodically or upon the complaints., which could be updated (weekly / daily, Monthly / Annually,
- all of control authorities had SOP for sampling and transportation to PFSL, where they used to take the sample randomly from the source, then it would be coded to be filled in the sampling form that contains details about the source and the product), then they send the sample under the appropriate conditions to the Laboratory with delivery form, where data would be filled in, where this control authorities would request appropriate test(s) for the product.
- Control authorities used to deal with non-conforming samples by many methods, such as (Dispose the product, Public Persecution, given a Warning to take a corrective action, or transferred to Customer Protection Department,

- All of control authorities used to keep records about failed sample for future analysis and improvement to intensify number of the taken sample at the next sampling plan.
- Control authorities used to request food tests that were not accredited by PALAC, since some of control authorities implemented all of food tests in the belonged laboratory, or because the requested tests are not accredited in all PFSL,
- About (33.3%) of control authorities used to send the doubted sample(s) to three laboratories randomly to confirm the accuracy of results in case of doubt, while the other (66.7%) did not dealt with the doubted test results at all, because the tests were conducted in laboratories accredited by an official government entity and follow-up laboratory tests are duly.
- All control authorities did not have an information communication agreement with PFSL.

The objective of reducing risk aims to provide adequate consumer protection that cannot be achieved effectively by merely sampling and analyzing the final food product. Therefore, the introduction of preventive measures in all stages of the food chain is essential to achieve food safety systems that continue to focus primarily on end product control. However, in Palestine, there is a lack of a clear sampling policy specifying the number of samples and frequency of sampling of each type of food. The policy and the frequency of sampling should be based mainly on the risk associated with the consumption of each type of food, previous analysis results, and the consumption rate.

4.2 SWOT Analysis

Since SWOT analysis defined as a compilation of the chosen company's: strengths, weaknesses, opportunities and threats (David, 1993). The research used the primary objectives of a SWOT analysis is to help PFSL to develop full awareness of all the factors involved in making a business decision, and to assess and develop the current status of these laboratories.

The research depended on the samples' answers and his registered notes while visiting the laboratories, in addition to information collected from other sources such as PALAC.

The following are the internal and external items in SWOT analysis. Hereby, a SWOT analysis had been developed to find out the internal factors (strengths, weaknesses) and the external factors (opportunities, threats) for PFSL.

4.2.1 Internal Factors:

Strengths:

1. There are many types of food safety laboratories established in Palestine (governmental, private, and municipality).
2. Five of the nine PFSL conduct most of the food tests (microbiological, chemical, and physical) related to food safety and food quality and have accreditation from Palestinian accreditation PALAC according to international standard for laboratories ISO 17025.
3. Most of PFSL provide testing services for all customers (public and private sectors).
4. Most of PFSL get financial support from many sources (ministries, NGOs, governmental institutions and private sources).
5. Most of PFSL have employees for quality control and quality assurance, and the quality procedures that are concerned in laboratory activities (internal / external).
6. Most of PFSL have procedure to train the new lab staff on the analytical methods and laboratory’s instructions.

7. Most of PFSL have power back-ups (uninterruptible power supply-UPS and/or generator) and air-conditioning systems. And used to purify and/or de-ionizing water in laboratory.
8. Most of PFSL perform periodical calibration internally (for PH-meter / autoclaves / incubators / the other devices in chemistry unit) only, while (thermometers / weight) calibrated externally, to ensure the precision and accuracy of test results.
9. Public PFSL used to receive the samples from official trained inspectors, while some of private laboratories provide sampling service (to ensure that the samples had been taken appropriately).
10. All PFSL have a specified procedure in registering and tracking the samples from the moment of receiving until issuing the certification. Big laboratories have an electronic tracking system (LIMS).

Weaknesses

1. Most of PFSL located in major cities, especially in Ramallah and Nablus Governorates. This is considered an obstacle for customers to reach the laboratory and may cause damage to the samples due to the distance or the presence of occupation barriers.
2. There is no research institute specialized in food safety testing in Palestine.
3. Four out of nine of PFSL were not accredited either nationally or internationally for food safety tests.
4. The accredited PFSL have a national accreditation valid for national use only, while the international trade required international recognition and accreditation.
5. No PFSL worked according to Good Laboratory Practice (GLP).
6. Not all PFSL have organized internal auditing regularly.
7. Not all PFSL participate in national/international inter-laboratory proficiency tests.
8. Not all PFSL use certified reference materials (CRMs).
9. Not all PFSL used to handle customers' complaints.
10. Not all PFSL have SOPs for all analytical methods.
11. No sub-contracted analyses found in PFSL.

12. Most of PFSL have no access to relevant literature (e.g. AOAC, ISO, EPA methods, scientific journals).
13. Some PFSL are unable to perform certain tests that are necessary for food safety, because of (lacking the materials, limited budget, or the complexity of managerial procedures, untrained employees, and expensive tests).
14. More than half of PFSL were facing difficulties in maintenance operations, since it needs continuous maintenance (periodically) and some of them need a long time to be implemented, that causes to stop using these equipment's.
15. Most of PFSL suffer from insufficient lab staff since recruitment procedures are complex, and the budget is low. They also suffer from a shortage of training for lab staff and do not have annual internal or external training programs for the staff, which kept their experience in place.
16. Most of PFSL considered small and have ten employees or less.
17. No periodic maintenance, whereas Internal and external maintenance done when an error occurred in an equipment. Also, a few PFSL have maintenance unit inside the lab.
18. PFSL have small areas, which limit the expansion of activities. And about half of PFSL did not have enough separate storage room for samples and materials.
19. Not all PFSL have enough refrigerators and freezers available for the storage of samples and chemicals.
20. More than half of PFSL suffer from lack of equipment because of a low budget.
21. PFSL do not determine Turnaround Time (TAT).

4.2.2 External Factors:

Opportunities:

1. The competition in the Palestinian market for food safety testing laboratories is very low, since there are only nine existing FSL, and about half of them had not gained the accreditation yet.
2. Accreditation fees are reasonable, so all PFSL can gain an accreditation certificate including at least important food safety tests.
3. The Existing PFSL could be expanded to add many demanded food safety tests at their laboratories.

4. The local food industry and the imported food product agencies are expanding which increase the need for request food safety tests.
5. Human resources are available for PFSL because there are many graduated students specialized in food and laboratory analyses, able to achieve a lot of food safety tests.
6. Official food inspector's send many food samples to accredited public and privet PFSL. Since there were only one food control authority had managed Central Public Health Laboratory, which gives the opportunity to transfer the samples to the private sector.

Threats:

1. There is no international accreditation body in Palestine, which decreases the acceptance of the PFSL test results internationally.
2. Less than half of PFSL had a coordination with local FSL. And there is no subcontracting between PFSL.
3. Occupation and the siege were the main obstacles that the laboratories were facing when transferring samples to the laboratories, and in providing the main materials necessary to perform food safety tests.
4. Some of food safety tests are very costly and rarely to be requested.
5. High cost of equipment, facilities / building, and other managerial preparations.
6. There were weakness in educational centers in Palestine that introduces specialized training courses in food safety tests.
7. There is no official authority and criteria available for licensing of food laboratory. And there is no monitoring authority had the right to supervise and inspect the performance of the Palestinian laboratory tests.
8. Some PFSL (especially in Gaza Strip) faced power cuts, which is considered an obstacle to the analysis process and may cause damaging to the samples and materials used to achieve the tests.
9. Most of food industrial companies established their own laboratories for food safety tests, and this decrease the number of requested tests from PFSL.

CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

Upon the importance of providing safe food, the Palestinian Standards Institution put many regulations and legislations to ensure the safety of food products from farm to fork. The control authorities (Consumer Protection – MONE, Environment Health Dept. - MOH, and Palestinian Standard Institution (PSI)) are the official bodies who are responsible of ensuring that these roles would be applied from all parties, while the (governmental / private) PFSL are responsible to perform food safety testing. At this content, the research tried to assess all PFSL according to international standards.

The study was applied on (9) PFSL that represented all working food safety laboratories in Palestine till the end of the year 2019, and (3) inspectors who represented control authorities in Palestine who were concerned in monitoring the safety of food product. To achieve the study goals, analytical approach was applied at the two samples, by developing two study tools (questionnaire 1+2) that have been distributed to them. Where these tools took into the account the international standards for food safety laboratories. The results would give a clear status of PFSL and control authorities, while recommendations would be provided to make a synergy between this status and the international standards related to food safety testing.

The findings approved that PFSL could reach the international standards at many aspects, although they face some of obstacles in developing their laboratories and expanding their activities.

The most important weakness at PFSL could be recognized from SWOT analyses, where these laboratories are not distributed at all cities in Palestine and the customers in the other cities suffer from the long distance to deliver their samples.

Despite the importance of the existence of a research institution related to analytical methods, it has been found that there was no such existing institute in Palestine, adding to that, not all of PFSL and performed tests were accredited, which might lead a decrease of accuracy of the analyses results, since there were no available International

Accreditation body that exists in Palestine. Adding to that, not all unaccredited PFSL implement quality standards. On the other hand, no sub-contraction had been found between PFSL.

PFSL had faced many gaps due to managerial and technical reasons, such as: (small businesses, unable to perform certain tests, insufficient materials, insufficient area, maintenance difficulties, no periodic maintenance, insufficient lab staff, insufficient training, insufficient equipment, and no specific TAT for tests).

On the other hand, PFSL faced many external threats, such as (occupation, siege, high costs of equipment and materials, and no existing international accreditation body). One of the major obstacles that faced food safety testing in Palestine was related to unavailability of licensing authority for food laboratories, which meant that there was no monitoring on PFSL.

5.2 Recommendations

Depending on the findings of the research, the researcher recommended the following:

1. The PFSL should follow the requirements and guidelines of international standards such as (ISO 17025 and GLP) in order to organize their work and reduce the error rate in the test results.
2. Accredited PFSL should increase the range of accreditation to cover all food safety tests. Also, non-accredited PFSL should seek to get accreditation.
3. Seeking to gain the international accreditation certificate.
4. Supporting the working lab staff with suitable training courses that concerned in food testing equipment (usage, maintenance, calibration).
5. Working on creating kind of coordination between PFSL, for better achievements.
6. Upgrading and modernizing laboratory equipment.
7. Identifying and selecting opportunities for improvement and implement any necessary actions through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

8. The PFSL should seek feedback, both positive and negative, from its customers to improve the management system, laboratory activities and customer service.

According to the findings, the researcher recommended that control authorities should achieve the following:

1. Create a cooperated database and subcontracts between food control authorities and PFSL.
2. Developing food control plans based on risk analysis.
3. Establishing a registration body for food laboratories.
4. Increasing their activities by adding monitoring activity on PFSL.
5. Establishing government food safety laboratories that had accreditation for all food safety tests.
6. Creating special legislations to assess the performance of PFSL.
7. Developing national food safety laboratory quality standards by policy-makers and regulators to ensure the accuracy of test results and increase the confidence of customers.

5.3 Future studies

1. Focusing on the assessment of certain sections in PFSL such as the chemistry section or microbiology section, considering the specific standards to be met in each section.
2. Assessment of food control system in Palestine.
3. Study the relationship between food control authorities and public health centers.

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APPENDICES

Appendix -A-

Interview Questionnaire on Food Safety Laboratories

This part of interview questionnaire will show the existing status (capability & capacity) and performance of food safety laboratories in Palestine, and mainly focused on laboratory accreditation and quality management, testing scope and sample capacity, instrumentation, facilities/ building and lab staff.

General information about laboratory	
Name of laboratory	
Location	
Telephone number	
Fax number	
Email address	
Web site	
Name of Laboratory director	
Type of laboratory	○ Private ○ Governmental ○ Academia ○ Research institute
If governmental lab: to which ministry?	
Please describe the main activities of the laboratory and Laboratory sections	
Who are your main customers?	

Quality system		
Is the laboratory accredited according to ISO 17025?	□ Yes	□ No
If yes, since when? And what is the name of the accreditation body?		
Is the laboratory working according to GLP?	□ Yes	□ No
Is a Quality manager/Quality team in place?	□ Yes	□ No
Is a Quality Manual present?	□ Yes	□ No
Are internal audits organized on a regular basis?	□ Yes	□ No
Have the laboratory participated in national or international inter-laboratory/ proficiency tests?	□ Yes	□ No
If yes, since when you are participating? Please, list the tests including the provider.		
Is there a process for handling complaints?	□ Yes	□ No
If yes, please describe briefly the procedure		

Methods of analysis	
Please, list available analytical methods.	
Are there SOPs for all analytical methods?	□ Yes □ No
How are non-compliant results confirmed?	
Are analyses sub-contracted?	□ Yes □ No
If yes, please list the sub-contracted laboratories and the criteria to choose them for sub-contracted analyses	
Is there coordination with local laboratories?	
Are certified reference materials (CRMs) used?	□ Yes □ No
Are there available high purity and/or de-ionized water in the laboratory?	□ Yes □ No
Has the laboratory access to relevant literature (e.g. AOAC, ISO, EPA methods, scientific journals) and/or electronic databases?	□ Yes □ No
If yes, please specify	

laboratory equipment	
Is an inventory of all equipment available?	□ Yes □ No
If yes, please provide a copy of inventory.	
If no, please list the main available laboratory equipment	
Do you have maintenance procedures (internally / externally)?	□ Yes □ No
What are the maintenance procedures? Internal/external? In general,	
What are the calibration procedures of the equipment? Internal/external? In general,	

Facilities/premises	
What is the surface of your laboratory in (m^2)?	
Does power back up exist? (uninterruptible power supply-UPS and/or generator)	□ Yes □ No
Are air conditioning systems available?	□ Yes □ No
Are enough separate storage rooms available for chemicals, samples and disposal?	□ Yes □ No
Are enough fume hoods available?	□ Yes □ No
Are enough refrigerators and freezers available for the storage of chemicals and samples?	□ Yes □ No
Is a centralized (external) gas supply?	□ Yes □ No
Is a cleaning schedule for the laboratory?	□ Yes □ No

Human resources (personnel)	
Number of total lab staff	
Is an annual internal and external training program for the staff?	□ Yes □ No
Is a procedure in place to train new employees on analytical methods?	□ Yes □ No

Sample Management	
Total number of food samples analyzed per annum (2018)	
Is the laboratory involved in sampling?	□ Yes □ No
If yes, are sampling procedures/ instructions/ SOPs available?	□ Yes □ No
How are samples registered and labeled at the laboratory? And How is the traceability of samples assured from reception to the reporting?	
Has the laboratory an electronic LIMS (Laboratory Information Management System)?	□ Yes □ No
If yes, please name the brand of the LIMS or do you use an in-house version?	
Are certificates/reports issued for each sample?	□ Yes □ No
Please provide a copy of examples of report	
How are samples archived after doing tests? For how long?	
How are reports archived? For how long?	
Is there a target for the turnaround time (TAT) for each test? Note: (TAT: time between reception of sample and reporting the results)	□ Yes □ No
How is the result delivered to customers usually? And in urgent case?	

Problems	**Existing**	**If exist, what are the reasons?**
Lack of materials	□ Yes □ No	
The inability to perform certain tests necessary for food safety	□ Yes □ No	
Insufficient equipment	□ Yes □ No	

Difficulties in maintenance operations	□ Yes □ No	
Power cuts	□ Yes □ No	
Water cuts	□ Yes □ No	
Insufficient lab staff	□ Yes □ No	
insufficient training of lab staff	□ Yes □ No	
Insufficient space	□ Yes □ No	
Other		
	□ Yes □ No	

Appendix -B-

Interview Questionnaire on Food Control Authorities	
General information	
Name of control authority	
Location	
Telephone number	
Fax number	
E-mail address	
Web site	
Director of the control authority	
Please describe the main activities of the control authority	
Is there any food safety laboratory belonged to your authority?	□ Yes □ No
Mention the names of laboratories that you are dealing with for samples testing?	
If yes, please list them and list the main tests done in each?	
Do you have any agreement with other laboratories?	□ Yes □ No
If yes: please list the name of the laboratories, and the purpose of the agreement with each.	
Do you have a plan for food sampling? (Frequency sampling)? List of Establishments inspected? Frequency of updates for the plan and the establishments list?	
Is there procedure (SOP) for sampling and transportation to laboratories?	□ Yes □ No
If yes, please describe briefly the procedure	
Mention the most frequent requested food safety testes?	
Do you have an official procedure for handling non-conforming samples? If yes, please explain.	□ Yes □ No
Do you keep records about failed samples (negative results) for future analysis and improvement?	□ Yes □ No
If Yes, explain the type of analysis	
Had you ever requested food tests that are not accredited by PALAC?	□ Yes □ No
If Yes, mention the name of the tests and explain why?	
Do you deal with complaints about the results of the tested samples? If yes, please explain.	□ Yes □ No
Is there agreement with Palestinian food safety laboratories about information communication?	□ Yes □ No

Appendix -C-

An example of a Palestinian accreditation certificate for a food safety laboratory

PALAC

Accredited Testing Lab.

Palestine Accreditation Unit
Ministry of National Economy
State of Palestine

Accreditation Certificate

The Palestine Accreditation Unit -PALAC- attests that the laboratory:

Scientific Center for Food & Drug Analysis
3rd floor of Nimer Building – Adl street
Nablus - Palestine

Is competent under the terms of ISO/IEC 17025:2017 to carry out the tests specified in the attached Accreditation Schedule No. "LAS-015" which is an integral part of this certificate and cannot be read without.

This Accreditation Certificate is valid until **20/05/2022**

Cert. No.: LAC-015

دولة فلسطين
وزارة الاقتصاد الوطني
وحدة الاعتماد
Accreditation Unit
State of Palestine

Chair of PALAC

Eng. Abdel Rahman Shtayeh

ملحق اعتماد

Accreditation Schedule
LAS-015

مختبر المركز العلمي لتحليل الأغذية والأدوية والسموم- نابلس

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Web Site :

Test Category	Materials/ Products Tested	Specific tests or properties measured	Standard/ Method Reference No.
Food	* General Food • Biology	- Total Plate Count - Total coliform - Fecal coliform - Yeast and mold	-BAM (2001) CH.3 -Microbes in action. 4th Edition (1991)) -Microbes in action. 4th Edition (1991)) -Microbes in action. 4th Edition (1991))
	• Chemistry	- pH of acidified foods. - Benzoic and Sorbic Acid Content in food. - Salt (NaCl) - Aflatoxin	-AOAC 981.12 (1998) -AOAC 983.16 (1998) -AOAC 923.03 & AOAC 937.09 (1998). -Detection & determination of aflatoxins using affinity chromatography. International journal of food science and technology (1988) 23. 479-485
	* Fat and Oil	- Peroxide Value of Oils & Fats - Fatty Acids in Oils and Fats*	-AOAC 965.33 (1998) -AOAC 969.33 (1998)
	* Meat & meat products	- Fat	-AOAC 991.36 (1998)
	* Feeds animal products	- Moisture	-AOAC 930.15 (1998)
	* Cereal products	- Ash.	-AOAC 923.03 (1998)
	* Juices & Soft drinks	- Brix Value.	-Instrumental manual method.

دولة فلسطين وزارة الاقتصاد الوطني وحدة الاعتماد Accreditation Unit State of Palestine

ملحق اعتماد

Accreditation Schedule
LAS-015

مختبر المركز العلمي لتحليل الأغذية والأدوية والسموم- نابلس

The Lab of Scientific Center for Food & Drug Analysis- Nablus

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Issue No : 1/2019
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Web Site :

Test Category	Materials/ Products Tested	Specific tests or properties measured	Standard/ Method Reference No.
Water & Waste water	* Water & Waste water • Biology	- Total Plate Count - Total coliform - Fecal coliform	-Microbes in action. 4thEdition (1991))
	• Chemistry	- Free and total Chlorine by special kit for chlorine (0.02 – 10.0 mg/l)	-Kit manual method (NANOCOLOR®).
Cosmetics & Detergents	* General Cosmetics & Detergent	- Total Organic Matter Content	-P.S 156-3 (1999)
	* Detergents	- NaCl content. - pH.	-P.S 156-06 (2001) -P.S 156-10 (2001)
	* Hypochlorite Solutions	- Active Chlorine Content in Sodium Hypochlorite Solution.	-P.S 68 (2001).
	* Toilet Liquid Detergent	- Analysis of HCl.	-P.S 204 (1999).

Chair of Palestine Accreditation Unit

دولة فلسطين وزارة الاقتصاد الوطني وحدة الاعتماد Accreditation Unit State of Palestine

تقييم قدرات مختبرات سلامة الأغذية في فلسطين

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اشراف: د. عزام صالح

الملخص

في فلسطين، تنمو صناعة الأغذية والصناعات الزراعية وتتوسع في نطاقها وتنوعها استجابة لمتطلبات السوق المتغيرة باستمرار. وبالتالي، لتزويد المستهلكين بالمنتجات الآمنة، تلعب مختبرات سلامة الأغذية دوراً حاسماً وتشكل أساس النظام الوطني لمراقبة الأغذية. الهدف من هذا البحث هو تقييم ممارسات الفحوص المخبرية ومدى تطبيق مختبرات سلامة الأغذية الرئيسية في فلسطين (سبعة مختبرات في الضفة الغربية ومختبرين في قطاع غزة) للمعايير والمبادئ التوجيهية المعترف بها دولياً.

لتحقيق الغرض من الدراسة، استخدم الباحث استبانات تركز بشكل أساسي على الجوانب التالية : ضمان الجودة ومراقبة الجودة وإجراءات الاختبار والأجهزة والمعدات المتوفرة والمرافق والمباني والموظفين وإدارة العينات والمعيقات. بالإضافة إلى ذلك، استخدم الباحث مقابلات منظمة مع ثلاث هيئات وطنية لمراقبة الأغذية للاستطلاع على ممارساتهم المتعلقة باختبار سلامة الأغذية وعلاقتها مع المختبرات المحلية لسلامة الأغذية.

تمت معالجة البيانات والمعلومات التي تم جمعها وتحليلها باستخدام برنامج SPSS. بالإضافة إلى ذلك، تم استخدام تحليل SWOT للحصول على فهم أفضل لممارسات المختبرات المستهدفة. و تم تلخيص النتائج الرئيسية على النحو التالي: (1) أن معظم المختبرات التي تم تقييمها لم تف بشكل كاف بمتطلبات المعايير والمبادئ التوجيهية الدولية المعترف بها مثل الأيزو 17025، (2) من بين تسعة مختبرات عاملة في فلسطين، خمسة مختبرات فقط حصلت على اعتماد محلي من قبل وزارة الاقتصاد الوطني ولم يشمل هذا الاعتماد جميع فحوصات الأغذية، بينما باقي المختبرات تقدم الخدمة دون حصولها على أي اعتماد، (3) لا يوجد تعاقد بين المختبرات في مجال الفحوصات، (4) شارك أكثر من نصف المختبرات في اختبارات الكفاءة الوطنية أو الدولية، (5)

خمسة مختبرات فقط لديها المعدات اللازمة لأداء معظم اختبارات سلامة الأغذية الكيميائية والميكروبيولوجية والفيزيائية، بينما باقي المختبرات تجري اختبارات ميكروبيولوجية أو فيزيائية فقط، (6) من حيث المرافق والمباني معظم المختبرات مصممة تصميماً جيداً ولكن ليس لديها مساحة كافية لتيسير عملها وتوسيع نطاقه، (7) ستة من تسع مختبرات تعاني من نقص الموظفين وخمسة منها تعاني من عدم توفر التدريب الكافي للعاملين في المختبر، (8) حوالي نصف المختبرات تقدم خدمة أخذ العينات وفق الإجراءات والتعليمات اللازمة، (9) تنفذ جميع المختبرات إجراءات لتتبع العينات من لحظة الاستقبال حتى إصدار تقرير النتائج، لكن ثلاث مختبرات فقط تستخدم نظام LIMS الإلكتروني (نظام إدارة معلومات المختبرات) للتتبع، (10) تواجه المختبرات العديد من الصعوبات لأسباب إدارية وفنية مثل: محدودية نطاق الأعمال وقلة الطلب على الخدمات، والتوزيع الجغرافي المحدود للمختبرات، وعدم القدرة على إجراء اختبارات غذائية معينة، وعدم كفاية مساحة المختبر، وصعوبات صيانة المعدات، وعدم الصيانة الدورية، وعدم كفاية طاقم المختبر، وعدم كفاية التدريب للعاملين، وعدم كفاية معدات الفحص، وعدم وجود وقت محدد لصدور نتائج الإختبارات، وعدم توفر بعض المواد، وانقطاع التيار الكهربائي، وعدم وجود هيئة اعتماد دولية للمختبرات في فلسطين، وعدم وجود جهة رسمية لترخيص مختبرات الأغذية، (12) من ناحية أخرى، لم يكن لدى اثنين من سلطات رقابة الأغذية الثلاث أي مختبر لفحص سلامة الأغذية، بالإضافة إلى أن جميع السلطات الرقابية ليس لديها خطة واضحة لأخذ العينات تحدد فيها عدد العينات التي يجب أخذها ووتيرة أخذها من المنشآت الغذائية. تبين أيضا أنه لا يوجد تبادل بيانات أو تحذيرات بين مختبرات سلامة الأغذية وسلطات رقابة الأغذية.

يتم تقديم العديد من التوصيات التي تستهدف كل من مختبرات سلامة الأغذية والجهات الوطنية لمراقبة الأغذية في هذه الرسالة. ركزت هذه التوصيات بشكل أساسي على استدامة الخدمة، وتعزيز كفاءة الاختبار، ورفع مستوى مهارات موظفي المختبر.

وفقًا لأفضل معرفة للباحث، تعد هذه الدراسة الأولى من نوعها في فلسطين ولم يتم إجراء أي دراسات سابقة لتقييم كفاءة مختبرات سلامة الأغذية. وبالتالي، يعطي هذا البحث فهماً أفضل للوضع الحالي ويلقي الضوء على بعض نقاط الضعف المتعلقة بالنظام الوطني لسلامة الأغذية.