Participants' Manual	Document Control ID Code: QSD-MNU-002-CQML Participants manual-V1.0

Topic & Purpose: Participants' Manual for CQML	**Review Period:** *4 years*
Location: Center for Quality in Medical Laboratories	**Distribution:** *Center documents and records cabinet and shared drive under "QSD".*
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Written by: **Lab supervisor /Director Deputy** Ziyad Khdour	**Related SOPs and documents:** See page#28 item# 10
Approved by: **Lab technician** Dua Mushleh	
Authorized and released by: **Lab supervisor /Director deputy**: Ziyad Khdour	
Replaces the version: NO	**Number of pages:37**

Table of Contents:

1. General Information (The history of EQAS)

1.1 Background:

The external quality assessment scheme is a self-funded "non-profit" organization hosted by the Faculty of Health Professions – Al Quds University. It was initiated in 1995 in cooperation with MAP – UK and the Palestinian Health Council to assess the analytical performance of medical laboratories. It was a supported project for three years. The program continued to operate till 2001, with support from the university. At the end of 2001, the program was interrupted due to political events and the inability to communicate effectively with laboratories due to the second Intifada. During 2009 - 2012 Continued work at the university and began work **Online.**

In 2012, the Center for Quality in Medical Laboratories (CQML) was established as an independent entity affiliated to Al Quds University at Al-Bireh city.

A memorandum of understanding was signed with the Palestinian Medical Technology Association (PMTA) and the Ministry of Health by which participation became **Mandatory** with symbolic Fees. The Program quickly expanded to include all medical laboratories in Palestine with over 600 participants. Till now, it is ~~now~~ the only EQA provider in Palestine. Full details of all the EQAS services and programs offered can be found on EQAS website https://eqas.alquds.edu.

1.2 Aim:

a. To provide professionally-led and scientifically-based EQAS services with a primarily educational objective, to help participants appraise their performance and monitor improvements.
b. To distribute EQAS Samples which are as closely as possible represent clinical specimens.
c. To distribute specimens to assess problem areas found in clinical labs.
d. To perform continuous assessment within rolling time windows of usually 4 round distributions per year, providing information on bias, Z-score and VIS - score through the use of consensus values.
e. To produce clear and informative reports which can be easily read and understood by different levels of laboratory staff.
f. To give information on method performance and instrument for the individual laboratory. This is important for comparing and evaluating methods and instruments.

g. To help to ensure clinical laboratory test results are accurate, reliable and comparable wherever they are produced.
h. To improve patient care through the expert design and delivery of EQAS schemes and the skillful interpretation and communication of the data they generate to all relevant stakeholders.

1.3 Location:

CQML is located at the Al Bireh Medical Center building, 3rd floor, Al Bireh, Palestine. While the IT Center and purchase unit are located at Said Khoury Building and Grants and Projects department at Al-Quds University in Abu Dees town.

1.4 Communications:

- By phone: The phone number is: 022414076 which is continuously manned from 08:30 to 15:00 h Sunday to Thursday. Callers will be asked about the nature of their request or enquiry, and will then be transferred to the appropriate member of the team. All callers will be asked for their name, lab code and for an indication of the nature of the call, before it is passed to the most relevant member of staff for attention. Most communications can be dealt with speedily and effectively by our highly experienced and knowledgeable administrative and scientific support staff without referral to the director. Callers can therefore be confident that they do not

have to speak to the director on each and every occasion. All contact information is logged and the outcome of calls and actions audited.

- By Fax CQML fax # 022411149
- By email: eqas@alquds.edu or
- By WhatsApp: 00972597601623
- By following our page on Facebook: Center for Quality Control in Medical Laboratories.

1.5 Staffing & Management:

CQML is directed by a Consultant Clinical Hematology Scientist with many years' experience of EQAS work. The Director is supported by the Deputy Director (Lab supervisor). Designation of CQML director by the dean of the Faculty of Health Professions.

Day to day management of CQML Quality is the responsibility of the Director. Day to day management of the individual EQAS services is the responsibility of the Lab supervisor and CQML staff.

The CQML Director, lab supervisor and their staff carry out sample preparation and distribution, data entry, report production and publications, communications and general clerical duties. All staff are employees of CQML and Al-Quds university and are solely employed in the provision of EQAS services. The IT Team is responsible for the development, implementation and maintenance of the internet services, Programing and Statistical data analysis program.

The Procurement Department is responsible for following up purchase requests, as well as sending quotations, analyzing them, and making evaluations for service provider

companies. While the Department of Grants and Projects is responsible for following up the Center's bank accounts and financial matters and disbursing petty cash to the Center for the purchase of urgent materials

1.6 Website

Information about CQML and the EQAS services provided can be found at the University Website https://eqas.alquds.edu under: Center for Quality in medical laboratories –Al Quds University.

1.7 External Regulation of Our Services (Accreditation):

CQML is seeking the accreditation by ISO/IEC 17043: 2023 – Conformity Assessment – General requirements for Proficiency Testing –with support from PTB of Germany.

1.8 Steering Committees & Specialist Advisory Groups:

All PT providers are required to seek advice from and report to Steering Committees and/or Specialist Advisory Groups. The EQAS Schemes of CQML is presently served by Steering Committee mainly from Al-Quds University and Ministry of Health (MoH) and the Palestinian Medical Technology Association (PMTA) which advises on overall policy matters.

2. Terms and Conditions of Participation

2.1 Eligibility:

CQML Quality services are designed principally for Palestinian Governmental, NGOs and private sector clinical laboratories serving clinicians and patients. Non-Palestinian clinical laboratories are also welcome to participate.

2.2 Registration:

The act of requesting registration or re-registering (whether by email, letter or by web form) confirms a participant's willingness to be bound by these terms and conditions. For Medical laboratories, the act of enrolling in any EQAS scheme confirms their willingness to be bound additionally by CQML Conditions of Participation for labs.

2.3 Subscription form:

The subscription form is sent after the laboratory contacts the center or sends an email wishing to participate in the quality control program (EQAS).

2.4 Period

The annual Subscription paid by participants through CQML account at Bank of Palestine, covers only one year of participation.

For existing customers, participation will be deemed to be continuous, unless notified in writing of any discontinuation after the end of participation date.

In the event of a participant failing to pay the annual subscription fee after one year of the due date, the CQML reserves the right to terminate the annual subscription without notice and the participant will be liable for the payment for services provided.

Participants wishing to cancel the program must provide written notification of cancellation.

Participants can join at any time throughout the year

The liability of CQML to the participant in any annual period resulting from or in connection with the provision of the Program to the participant, shall under no circumstances exceed the amount of the Annual fee paid by the participant

No refunds are provided for termination during the enrolment year

User accounts will remain active for 4 weeks following the cancellation date. After that period, requests for historic reports will need to be submitted to CQML and charges will apply for this service.

2.5 **Enrolment Procedure**:

Participation begins at the first distribution following receipt of fully completed enrolment Subscription form sent in response to a formal request to participate.

Subscription forms gather full details of the participating laboratory, Instruments and the methods it uses for the analyte(s) concerned. (Annex A)

As indicated above, enrolment may take place at any time. Visit http://eqas.alquds.edu /contact-us for information about how to contact us with enrolment requests.

Upon enrolment, each participant is given a unique laboratory code by CQML, which remains associated with that participant indefinitely.

Reattribution of codes and data can be accomplished where laboratories close, merge or unmerge. Participant codes must not be disclosed to third parties

2.6 Confidentiality

Lab Information anonymity is preserved on reports and documentation made available in the public domain (or to other participants) by allocating each laboratory with numerical codes. The codes are unique to the laboratory and used in all correspondence. There are secure and controlled storage areas for all confidential data. All confidential papers that are not stored are shredded prior to disposal.

The EQAS code number and name of the laboratory and the assessment of individual performance are confidential to the participant and will not be released by CQML without the written permission of the Head of the laboratory to any third party.

When the PT provider is required by law or authorized by contractual arrangements to release confidential information, the client concerned will be notified of the information released,

2.7 Use of Residual Material

The materials distributed are provided as specimens for the sole purpose of testing of analytes, at the recipient's laboratory during the current round.

Most of the clinical material is collected, prepared and manipulated in house, including homogeneity and stability testing. No claim is made that they may be suitable for any other purpose at any other point in time.

2.8 Repeat Samples

Limited numbers of samples from a particular distribution are usually available to participants who may wish to check aberrant results or evaluate new methods. CQML reserves the right to ask why repeat samples are needed and limit their supply if there is no clear idea or information about that.

2.9 Reporting of Results

All participants are expected to return results promptly within the specified reporting period of results.

2.10 Lab information data

Participants are responsible for ensuring that the contact person data (including mobile number Email), method and reporting units, information held by CQML is valid and up-to-date. All information about the Name of Method and Instruments, and unit of reporting concentration, can be communicated using the website methods and instruments update facility page. Participants need their usernames, and password to use this facility.

3 Materials

3.1 Sources of Blood and Serum

The majority of serum used is obtained from National Blood Bank whom CQML have a contract with. Some schemes require serum or EDTA blood from patients either collected specially by collaborating with some labs or by CQML itself (e.g. glycated hemoglobin).

3.2 Source of Other Body Fluids

These are obtained either from healthy volunteers or from patients through special arrangements with collaborating participant laboratories (e.g., Urine sample).

3.3 Safety

Blood collected by the National Blood Bank is tested and it is safe (as it is used for transfusion). Other materials or body fluids are both specially tested after obtaining, and accompanied by informed consent from volunteers.

3.4 Initial Analysis & Storage

Primary materials are stored appropriately according to their matrix (so as not to affect the critical analytes) after testing samples for safety procedure, and according to accepting and rejecting criteria.

3.5 Pool Processing

The pooling process is done for samples prior to sample preparation.

3.6 Participant Handling and Storage of EQAS Materials

It is recommended that EQAS samples should be analyzed immediately upon receipt. Where this is not possible, the samples should always be handled and stored by participant laboratories as closely as possible to the way they handle and store patients' samples. The length of time in storage should be kept to an absolute minimum and where the specimens have been refrigerated, the lab should follow the instruction sheet for each specimen prior to analysis.

3.7 Transport of samples

Where EQAS samples should be treated as patient samples and are transported according to local transport procedures. CQML have tested the integrity of specimens during transportation and can assert that the quality of EQAS samples is not ~~adversely~~ affected when transported via ice box bag.

4. Program Design

The matrix, frequency, number of samples, and analyte list for each scheme are detailed in the CQML Website. Instructions for use and stability of the samples are available in the Intended Use documents. Statistical methods, the evaluation criteria and example reports are available in the Interpretation of CQML Reports for Laboratory. These documents can be read from http://eqas.alquds.edu

4.1 CQML website

CQML recognizes the importance of the Internet for communication with and provision of services to participants.

A copy of the Instruction Sheet of samples is presented on the website. Instructions to the participant lab on how to treat samples are also present on the website under instruction sheets for each scheme. Time schedule distribution tables are present on the website.

Results can be returned to CQML by self-web entry, and if a problem appears with the lab in entering data, the lab can send it via fax, e-mail, WhatsApp or telephone.

The default option is web entry. Instructions for entering results via the web are available from CQML on the resource page at http://www.eqas.alquds.edu, web page-data entering

The deadline for phone, e-mail or faxed results must reach CQML by 2.00 pm on the "end period" date.

4.2 Reporting Units of concentration

The SI Units should be used whenever possible. Please ensure that the results are entered for the specified units on the web page. Results entered using incorrect units will not be converted unless it is made clear what the units used.

4.3 Instruments and test methods

Lab is responsible for defining instruments and methods used in each test which can be entered and modified as mentioned above (2.9).

4.4 Amendments Prior to Data Analysis

Participants who discover an error in their reported results before the reporting deadline can amend their results via the online service or call the CQML at any time whilst the distribution is open.

4.5 Late results

All EQAS programs have a minimum 3 – 4 weeks return window from the "start date", which is the date of dispatch from CQML. Please ensure that the results have been returned by the "end period" date. EQAS users will not be able to enter any results after this date." In exceptional circumstances, CQML can enter results after this date for ~~you~~ the participant if it is possible and after approval from the IT center. All reports should be run after this "report date". Please contact CQML for advice.

4.6 Collusion and Falsification of Results:

It is the responsibility of the participating laboratory to avoid collusion of results. Collusion between participating laboratories will lead to the exclusion of the laboratories' results from the reports. In addition, a laboratory found to be falsifying results will have its results excluded from the reports.

5. Operations

5.1 Distribution Round

CQML has four distribution rounds per year, each round contains different scheme samples according to the guideline of the number of samples that should be distributed per year, see Table 1.

Table 1: Scheme Distribution and number of samples

#	Scheme	# of samples /year	Type of scheme
1	Clinical Chemistry	8	Quantitative
2	Clinical Hematology &	8	Quantitative
3	Urine dipsticks	8	Qualitative
4	Hormonal Immunoassay	4	Quantitative
5	Clinical Coagulation	4	Quantitative
6	HbA1c	4	Quantitative
7	Blood Group	4	Qualitative

5.2 Distribution Dates

The schedule for the current calendar year (and the next year when known) is available at the webpage: eqas@alquds.edu, but dates may be subject to minor changes depending upon operational circumstances.

5.3. Methods & Instruments Classification

A crucial element of participation for all schemes is the correct assignment of method and instrument names, since performance scoring is method-based or instrument-based, and the provision of accurate instrument and method-related information is an important element of the service. It is the participant's responsibility to choose their methods and instruments. Our method and instruments update service is web-based and is accessed online via the 'Methods and instruments' button on the main page.

5.4 Packaging & Distribution

All tubes and vials are labeled with the type of scheme, storage temperature, analyte (where appropriate) and sample number. The Distribution Schedule for all samples is available on the CQML website. Once the specimens have been packaged, the CQML sends sms for MoH Directorates and labs to receive samples from the center. If for any reason specimens are not received, not received when expected, or are damaged upon receipt, notify CQML via one of the methods listed under 1.4 Communications.

5.5 Sample Handling

The general rule is that participants should treat EQAS samples identically to those from patients. It is recognized that sample tubes and vials are different and multiple samples may be received for certain schemes. In order that there should be uniformity of handling amongst participants, it is recommended that if an assay is not to be performed on the day of receipt, sample vials and tubes should be stored at +2-8 °C until the time of assay. The length of time for which the specimens are stored should be kept to an absolute minimum. Unless instructed otherwise, participants should ensure that all parameters in one scheme are done at the same day, with the same batch of reagents, and in the same analytical 'run', batch or calibration cycle, to ensure that unknown additional variability is not introduced. Once analysis is complete, please retain any residual EQAS material for troubleshooting purposes. Laboratories should store samples as they normally would for each type of scheme (i.e., serum should be stored in the freezer), but in the absence of a local protocol it is recommended that the storage conditions are followed as CQML recommended.

6. Data Processing

6.1 Data Handling

All Scheme data are held on secure network servers which are backed up daily. Data processing is performed using EQAS Oracle software modules which have been developed in association with Said Khoury Information Technology Center. This allows all schemes to be optimally configured according to CQML protocol

6.2 Calculation of "Target Values"

Participants' results are evaluated by comparing them to the consensus mean calculated according to ISO 13528. All participants are registered on each program according to their chosen parameter, method, instrument, unit, and measuring temperature (where appropriate). For a given sample and parameter, the results returned are compared to the mean for comparison to generate performance statistics. The mean for comparison may be the Instrument, the Method means, or the All Methods group of results, depending on the scheme and number of results. The minimum number of results required to generate a mean for comparison is 5, as agreed by the CQML staff. If there are less than 5 results in any category, the lab results will be compared to the "All methods" mean.

6.3 Calculation of Mean for comparison, Standard Deviation and Exclusion of Outliers

Results are entered into the CQML database, and then processed to generate statistics, following manual de-activation of gross outliers. For each instrument, method and all methods group, the mean and standard deviation (SD) are calculated and at this point Five SD Criteria are applied to identify and exclude statistical results from the

calculations. Then mean and standard deviation recalculate and each result above or below 3 SD will be excluded .Finally the mean and SD are recalculated after the outliers have been excluded.

6.4 Processing Surveillance

As each distribution is processed, CQML carefully checks the resulting data for integrity and consistency of results, and any unexpected shifts or non-agreement in values which might appear. If any are identified, the CQML staff is contacted so that the findings can be discussed and a preliminary brief report can be made. Sample reports are then prepared and parameters for graphic, chart and tabular data checked and adjusted where necessary. Anomalies are corrected before reports are published.

7. Reports

7.1 Distribution of Reports

The default status for report distribution is 'paper-free'. Participants may download their reports from the website as pdf and Excel files from Summary reports.

7.2 Report Format

Schemes' reports are the main interface with participants, and a great deal of effort has gone into making these informative and easy to interpret.

All scheme reports are generated as A4 size, in PDF format, Excel files and Images, which display the data in a number of discrete tabular and graphic shared across related schemes.

All report contains the following features (See Annex C)

- Scheme name
- Lab Name
- Sample number
- Analyte test
- No of respondents
- Lab result
- Mean (instrument and method means)
- Standard deviation
- CV%
- Outliers
- Deviation Index
- VIS (Various Index Score)
- MVIS last 8 sample (Mean Various Index Score)
- Bias%
- Excluded values
- Rating, i.e., Good, Satisfactory, Questionable or Unsatisfactory
- Histogram of all results (method group, Instrument,peer group(instrument and method) and individual results marked)
- Graphical indication of DI performance scores over time for each test.
- Measurement Uncertainty

7.3 Performance certificate

A performance certificate is issued at the end of each Gregorian year to the laboratories, which have committed to sending 75% of the sample results for each scheme, and this certificate is based on the results of VIS.

8. Complaints and Appeals Procedure

8.1 Definition

A complaint is considered to be any communication, written or verbal, from internal or external sources indicating deficiencies relating to the identity, quality, durability, reliability, safety, effectiveness or performance of the EQAS service. Formal complaints and other communications which point out deficiencies, difficulties or problems (which are classified by CQML quality as errors) are recorded together with any response or action taken by CQML. These are audited by the director or lab supervisor.

8.2 Types and the process of making a Complaint

Most problems experienced by participants consist of minor misunderstandings or problems with specimens and reports, or data entry which can usually be resolved over the telephone by any member of staff. If difficulties persist, then participants with continued justified cause of complaint about any aspect of the service should communicate their concerns immediately to the CQML lab supervisor, preferably in

writing (email or letter) though a preliminary telephone call may assist in clarifying the issue and establishing the requisite action.

Where the complaint is about scheme logistics and performance assessment then the lab supervisor is the appropriate point of first contact.

If matters remain unresolved, or the action taken by CQML is not satisfactory to the complainant, the next step is to refer the complaint to the CQML director and if who can communicate it to an expert.

8.3 Appeals Against the Evaluation of Performance

If there is an appeal against the evaluation of the performance, please contact us via any of the routes described in item *1.4 Communications*.

The appeal will be handled according to CQML complaints and appeals procedure. With regards to complaints against the evaluation of the performance, CQML Director's opinion will be the final decision.

8.4 Advice on the interpretation of the statistical analysis

in case of unsatisfactory results please call CQML for helping and advice

9. Footnotes

9.1 Feedback

This Manual has been made as comprehensive as possible, but it is appreciated that revision may be required to reflect progress. Participants are invited to make comments and suggestions, not only on the Manual but any aspect of our scheme program or procedures, so that amendments may be made for the next version. Please contact CQML with your notes & suggestions via CQML e-mail: eqas@alquds.edu

9.2 Acknowledgements

The continued loyalty of all participants, which has enabled CQML to develop and expand to meet the challenges of the new EQAS environment, is acknowledged. The careful work of CQML staff, the support of PTB, MOH, PALAC, PMTA and advice from members of expert committees and professional bodies are acknowledged.

CQML is grateful to our University - Al Quds University and to the continuous support they provide

9.3 Manual copies

This Manual, This document is the current definitive version of the Participants Manual and may be downloaded or printed by CQML Documents for their personal use.

10. References

1.ISO 17043:2023: Conformity assessment — General requirements for the competence of proficiency testing providers

2. ISO 13528:2022: Statistical methods for use in proficiency testing by interlaboratory comparison

3.WHO. Manual for organizing a national external quality assessment programme for health laboratories and other testing sites. WHO_EQA-Manual_2016

11. Annexes

11.1 Annex A

Lab participation form				
FOR-LPR -001- Lab participation form-V1.0	Version#: 1	Issue date: 1/2020	Language : English-Arabic	
Subject form: نموذج الإشتراك السنوي	File No: **FOR-LPR -001- Lab participation form-V1.0**	Pages # :3		Related SOPs&Documents: : QSD-PMA-002-CQML Participants manual-V1.0 QSD-QMA-001-CQML Quality manual-V1.0
Prepared by: CQML staff	Verified by: CQML staff	Qualified by: CQML staff	Approved by: CQML manager	

نموذج اشتراك لسنة 202X

في برنامج الرقابة النوعية الخارجية للمختبرات الطبية

اسم المؤسسة \ المختبر:

عنوان المؤسسة:

هاتف المؤسسة: البريد الالكتروني:

فاكس المؤسسة: واتساب:

اسم الشخص المرخص للمختبر : رقم الجوال:

اسم الشخص المكلف بالاتصال: رقم الجوال:

فترة الاشتراك من تاريخ الإنضمام للبرنامج: ---/---/ 20—إلى --/ --/ 20--

البرامج التي يشمل الاشتراك بها يجب وضع إشارة(X):

الرقم	البرنامج	وضع إشارة X
1	Clinical chemistry	
2	Clinical Hematology(CBC	
3	Urine dipsticks	
4	HbA1c	
5	Coagulation	
6	Hormonal Immunoassay	
7	(ABO) Blood Group	

توصيل العينات و وآلية دفع الاشتراك:

طريقة توصيل العينات: من خلال مديريات وزارة الصحة الفلسطينية أو استلامهم من المركز مباشرة

تكلفة الاشتراك: 200 دولار سنويا للمختبر الواحد **(يرفق وصل الدفع مع النموذج فاكس (02/2411149 او الايميل *eqas@alquds.edu:* أو عبر الواتس اب *00970598583807***

رقم حساب الرقابة النوعية للطب المخبري لدى **بنك فلسطين** رقم
الحساب البنكي(ايبان)PS65PALS04700**575691**0013000000

يلتزم المركز بالنقاط التالية:

- تقديم الخدمات التي يشملها الاشتراك في البرنامج:

*توفير ثمانية عينات سنويا لكل مختبر مشارك. و تشمل كل عينة: عينة دم لفحص الدم الكامل وفصيلة الدم (Stabilized Whole blood sample for Complete blood count testing) و عينة مصل مجففة لفحص كيمياء الدم (Lyophilized serum sample for chemistry analysis) وكذلك عينة بول (Urine) .
*توفير أربع عينات سنويا لفحص السكر التراكمي (sample HbA1c Fresh).
*توفير أربع عينات مجففة سنويا لفحص تجلط الدم (Coagulation lyophilized sample).
*توفير أربع عينات مجففة سنويا لفحص الهرمونات (lyophilized sample Hormonal Immunoassay)
*توفير أربع عينات فحص فصيلة الدم (ABO stabilized sample)
*تحليل النتائج لكل عينة و توفيرها للمشتركين من خلال الصفحة الالكترونية للبرنامج.
* يعطى المختبر **شهادة مشاركة** بالاضافة الى **شهادة اداء** عند إعادة تجديد الاشتراك من أجل استخدامها كوثيقة للترخيص لدى وزارة الصحة الفلسطينية.
*لمعرفة آلية تقييم النتائج يرجى الاطلاع على نموذج Participant Manual
*تقديم المشورة الفنية لتفسير النتائج و طريقة تصحيح الفحوصات المعنية عند الحاجة من خلال التواصل بالبريد الالكتروني, التلفون أو الزيارات الميدانية.
* في حال تم تغيير أي من البنود السابقة للخدمات التي يشملها الاشتراك في البرنامج يتم إعلام المختبر المشارك من خلال ارسال كتاب رسمي او الاتصال به أو من خلال التعميم على موقع المركز
* في حال تم قبول المختبر في البرنامج واراد عمل تعديل على أحد البرامج التي ينوي المشاركة بها يتم الطلب منه باعادة ارسال نموذج الاشتراك مرة اخرى.

- السرية التامة : يعطى كل مختبر يشترك في البرنامج رقما خاصا به lab code number ومعروفا لمدير المختبر ومنسق البرنامج فقط, ولا يحق لأي شخص سواهما معرفة هذا الرقم إلا بعد موافقة مدير المختبر المشارك . إذ يستخدم هذا الرقم لأغراض الاتصال بين البرنامج و المختبر.
- في حال تم طلب أي معلومة سرية تخص المختبر من قبل جهة رسمية/ قانونية فإنه لا يتم تزويد الجهة الرسمية بأي نتيجة الا بعد اعلام المختبر المشارك بطبيعة ونوعية المعلومة.

- في حال تم استلام أي معلومة تخص المختبر المشارك من جهة أخرى غير المختبر المشارك فانه يتعهد المركز بالحفاظ على سريتها وعدم الإفشاء بها مع التحفظ بهوية الجهة التي تم استلام المعلومة منها.

المختبر المشارك يلتزم بما يلي:

- أن يعامل العينات التي يرسلها البرنامج مثلما يعامل عينات المرضى التي يستقبلها المختبر أثناء العمل اليومي.
- أن يزود منسق البرنامج بالمعلومات المطلوبة عن الطرق والأجهزة المستخدمة في فحص العينات وذلك لتسهيل التحليل الإحصائي للنتائج, وان يعلم البرنامج أيضا بأية تغيرات قد تطرأ مستقبلا .
- أن يجري الفحوصات المطلوبة لعينات البرنامج في المختبر باستخدام الطرق والأجهزة التي أعلن عنها عند الاشتراك في البرنامج.
- أن يرسل نتائج فحوصات عينات البرنامج في المواعيد التي يحددها البرنامج بشكل سري ومن خلال الصفحة الالكترونية للبرنامج.

- دفع رسوم الاشتراك في البرنامج علما انها غير مستردة في حال تم الانسحاب من الاشتراك
- الاشتراك في البرنامج يتم تفعيله تلقائيا كل عام مع دفع رسوم الاشتراك السنوية وارسال صورة عن وصل الدفع
- يمثل التوقيع على هذا النموذج إقرارا من المؤسسة\المختبر بالاشتراك في برنامج الرقابة النوعية الخارجية للمختبرات الطبية للفترة المحددة أعلاه وأن ألتزم بالنقاط المحددة في الصفحة الثانية، وكذلك إقرارا من مركز الرقابة النوعية في الطب المخبري بتقديم الخدمة والالتزام بالنقاط المبينة في الصفحة الثانية.
- **المؤسسة \ المختبر المشترك:**
- اسم الشخص المسؤول \ التوقيع

مركز الجودة للمختبرات الطبية

جامعة القدس

11.2 Annex B

EQAS Instruments & Methods Sheet

Lab name:	
Lab code:	
Password:	
فاكس وايميل مركز الجودة لإرسال المعلومات	02/2411149 eqas@alquds.edu

#	Test name	Method Type	Primary Instrument	Secondary Instrument
1	Glucose			
2	Creatine			
3	Uric Acid			
4	GOT			
5	GPT			
6	Urea			
7	Cholesterol			

8	Triglycerides			
9	Alkaline Phosphatase			
10	Bilirubin			
11	Calcium			
12	Albumin			
13	Creatine kinase CK			
14	HDL-Cholesterol			
15	Phosphorus inorganic			
16	Amylase Total			
17	Sodium			
18	LDL Cholesterol			
19	Iron			
20	Potassium			
21	Magnesium			
22	Direct Bilirubin			
#	**Test name**	**Method Type(Instrument Name)**	**Primary Instrument**	**Secondary Instrument**
19	WBC			
20	Hb			
21	RBC			
22	HCT			
23	MCV			

24	PLT			
25	MCHC			
26	MCH			
27	PT			
28	APTT			
29	INR			
#	**Test name**	**Method Type**	**Primary Instrument**	**Secondary Instrument**
30	HbA1c			
31	B-HCG			
32	Prolactin			
33	TSH			
34	FSH			
35	LH			
36	FT4			
37	FT3			

Urine dipsticks

#	Test name	Name of urine dipsticks		
38	Glucose mg/dl (mmol/L)			
39	Ketone mg/dl (mmol/L)			
40	Blood cells/µl			
41	Protein, mg/dl (g/L)			
42	Urobilinogen,mg/dl (µmol/L)			
43	Bilirubin,mg/dl (µmol/l)			
44	Nitrite			
45	Leukocytes, cells/µl			
46	pH			
47	Specific Gravity			
48	Blood Group(A,B,AB,&O)			
49	RhTyping(Positive or negative)			

Annex 11.3 C summary report

مركز الجودة للمختبرات الطبية
Center for Quality in Medical Laboratories

Scheme: Clinical Hematology
Number: 115 - form (1)
Test: WBC 10*9/L

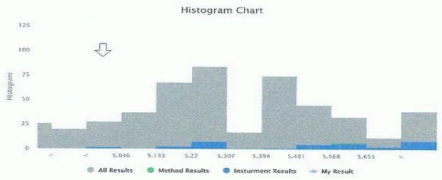
Lab Name: [redacted]
18/Nov/2024

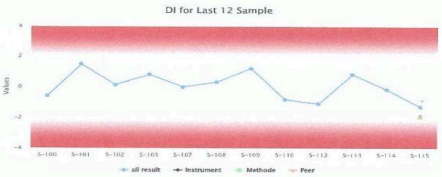
Summary Report

Analyte	No. Resp	Mean	Exclude	Outliers	Your result	DI	SD	CV%	VIS	Um	M VIS Last 8	Bias%	Comment*
ALL	466	5.316	7	13	5	-1.322	0.239	4.5	66.67	0.014	177.78/4= 44.45	-6	Satisfactory
INST	37	5.521	0	0	5	-1.923	0.271	4.9	100	0.056	200/1= 200	-9	Satisfactory
METHOD	36	5.523	0	0	5	-1.989	0.263	4.8	100	0.055	100/1= 100	-9	Satisfactory
PEER	34	5.527	0	0	5	-1.952	0.270	4.9	111.11	0.058	111.11/1= 111.11	-10	Satisfactory

Method Compare Report

Method	No. Resp	Mean	Exclude	outliers	SD	Um
Abbott Cell-Dyn	15	5.267	1	0	0.190	0.058
Abbott Cell-Dyn Ruby	6	4.400	0	0	1.338	0.631
Diatron	10	5.250	0	0	0.345	0.127
Dymind	8	5.218	0	0	0.305	0.123
Human Humacount Series	52	5.283	0	2	0.331	0.057
Linear series	20	5.102	0	2	0.171	0.048
Medonic M series	96	5.380	0	0	0.246	0.031
Mindray	11	5.105	0	0	0.432	0.152
Mispa count [AGAPPE]	8	5.515	0	0	0.513	0.207
Nihon Kohden Celltac Alpha	31	5.314	0	0	0.196	0.044
Nihon Kohden Celltac Alpha6510	82	5.349	1	1	0.138	0.019
Nihon Kohden Celltac Es	18	5.233	0	0	0.171	0.050
Nihon Kohden celltac G(9100)	11	5.211	0	0	0.271	0.096
Rayto series	11	5.098	0	0	0.229	0.081
Siemens/Bayer Advia	7	4.896	0	1	0.630	0.269
Spinreact	13	5.319	0	0	0.318	0.101
Sysmex KX Series	12	5.333	0	0	0.330	0.112
Sysmex XN-L Series	4	5.460	0	0	0.159	0.089
Sysmex XP Series	36	5.523	0	0	0.263	0.055
Sysmex XS series	3	5.287	0	0	0.327	0.191





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