



EQA/PT CATALOGUE

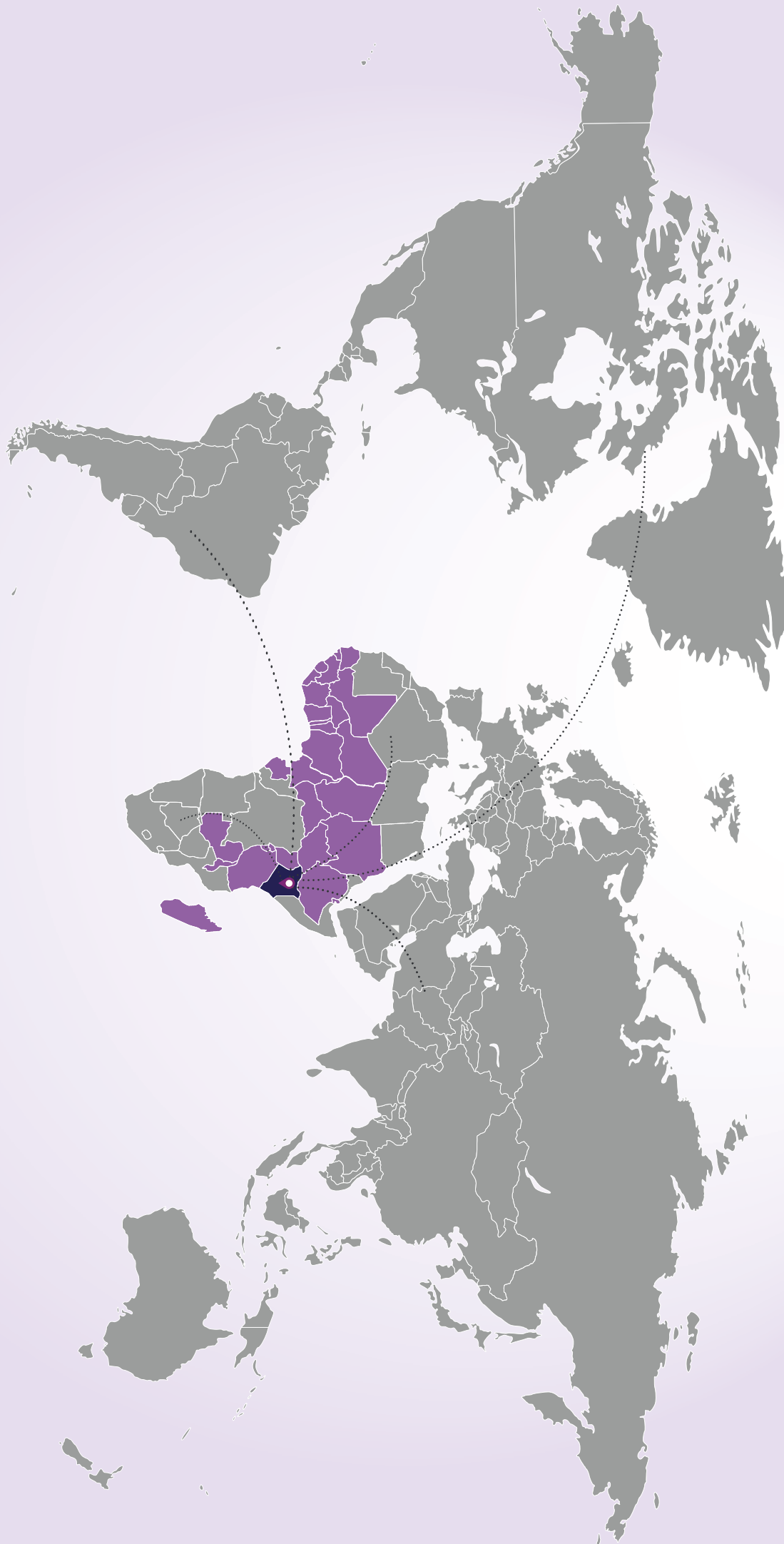


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INTRODUCTION

HuQAS (Human Quality Assessment Services) is a Non-Governmental Organization (NGO) that has been offering Proficiency Testing Services (EQA) and related Technical training to Public and Private Medical Laboratories since the year 2000. HuQAS is headquartered in Nairobi Kenya with EQA services spread in various African Countries and collaborations in North America and Europe.

The organization has dedicated resources and facilities to enable seamless operations of its core functions and these include an administrative office, ultramodern research and development laboratory, a training center, storage facilities, a nerve center for technical support and above all a well-trained and experienced staff including a mix of technical experts.

Accreditation to ISO/IEC 17043:2010 has enabled the organization establish a robust quality management system; build a culture of excellence, fault-proofing mechanisms and focus on the customer as the epicenter of its activities.

HuQAS Objectives. As an external assessment scheme, HuQAS objectives include:

- * To assist in the determination of the quality performance of individual clinical laboratories, as well as monitoring their continuing performance improvement.
- * To offer objective evidence of laboratories' analytical performance.
- * To identify inter-laboratory differences in various test parameters
- * To identify specific problems within participating laboratories that may relate to instruments, reagents or personnel and initiating remedial actions.
- * To build confidence in the quality status of the laboratories among doctors and patients.
- * To assess laboratories' ability to perform tests competently as per their stated internal quality goals and the requirements of regulatory and/or accreditation bodies.

HuQAS Annual Scientific Conference.

www.huqas.org/conference.

**SAVE
THE
DATE**

Welcome to the Annual HuQAS Scientific Conference, a premier annual scientific event where laboratory excellence meets healthcare transformation. This dynamic event brings together scientists, technologists, healthcare providers, policymakers, and industry leaders to exchange insights, inspire innovation, and forge impactful partnerships.

Through focused sub-themes ranging from EQA and QC best practices, clinical methods advancement, and disease surveillance, to POCT, QMS culture, and emerging lab technologies, innovations the conference champions the critical role of laboratory science in improving patient outcomes and strengthening health systems.

Join us in shaping the future of diagnostics and advancing quality across every level of care.



CONTINUOUS PROFESSIONAL DEVELOPMENT JOURNEY TO LEARNING

Unlock and discover new skills through the HuQAS Continuous Professional trainings and education!

HuQAS has training options to suit every participant. From new user courses in a classroom environment at our HuQAS Training Center, to customized onsite training by our experienced scientists in the comfort of your own lab.

Through education, you will gain knowledge and insights into the latest techniques, not only increasing your confidence, but also unlocking the full potential of your laboratory.

HuQAS offers the following training through a yearly calendar as well as on request (Onsite, at the HuQAS training center or virtually)

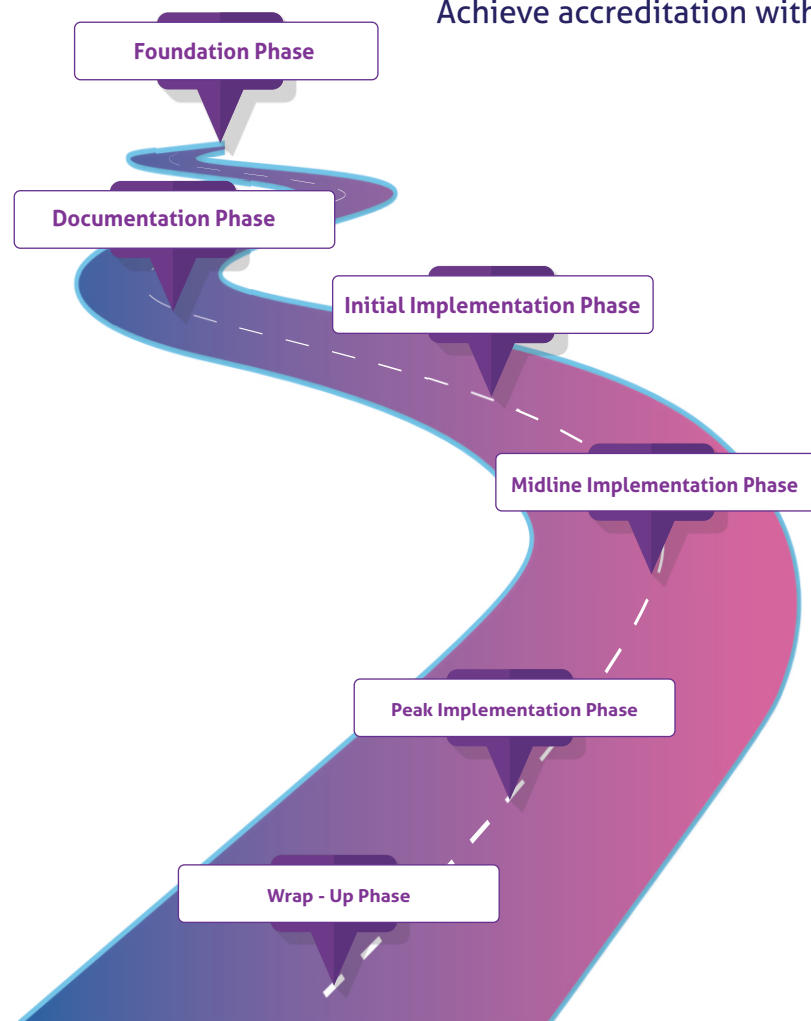
- Advanced Root Cause Analysis & CAPA Training
- Peripheral Blood Film Competency Training
- Good Clinical Lab Practice Training
- ISO 15189 Internal Auditor Training
- ISO/IEC 17043 Proficiency Testing Provider (PTP) Course
- Method Validation, Verification and Uncertainty of Measurements for Medical Laboratories
- Internal Audit for Proficiency Testing Laboratories Based on ISO 17043:2010
- Biosafety and Biosecurity Training
- ISO 13528 Awareness and Advanced Training
- Malaria Microscopy Refresher
- Andrology Training
- ISO 15189:2022 Transition and Implementation
- Phlebotomy Refresher Training
- TB Microscopy Refresher Training

THE MENTORSHIP JOURNEY TO ACCREDITATION

Laboratory accreditation mentorship program, based on ISO 15189 International Standard.

Strengthening the quality and capacity of our medical laboratories.

Achieve accreditation within **6 - 12 months**.



WHY THE HuQAS MENTORSHIP PROGRAM

- Ample contact hours between our mentors and the mentees hence a shortened project duration.
- Access to a well-versed team of mentors dedicated to your laboratory.
- Active involvement of our renowned team of Advisory Board Members to the mentorship process.
- Opportunity for Exchange of best lab practices among pathology and laboratory medicine peers under the HuQAS EQA programs.
- Integration of other laboratory related guidelines e.g., CLIA, CLSI, CAP, OSHA, JCIA, SafeCare, etc bolstering patient care and safety.



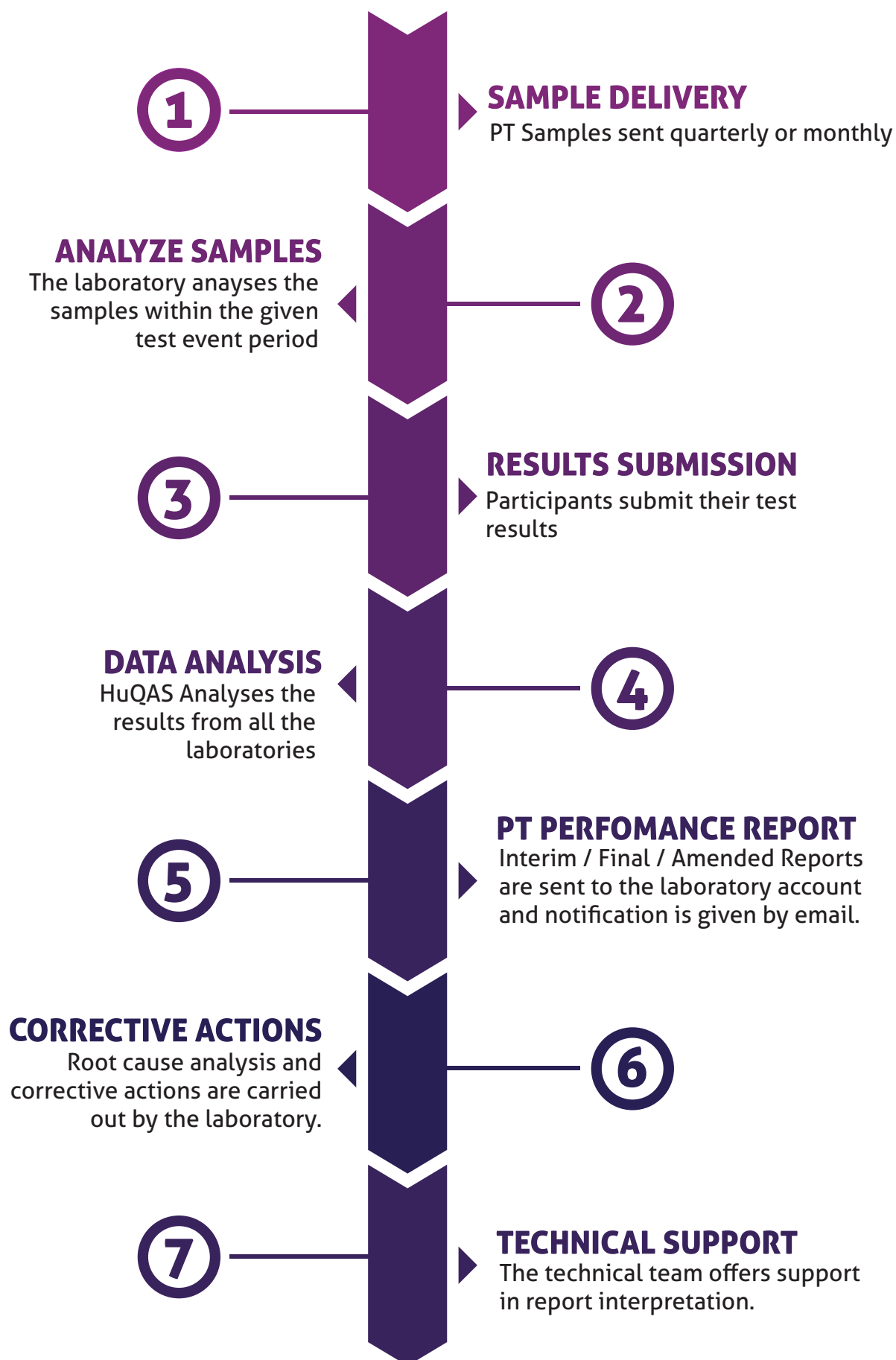
HuQAS EQA PROGRAM INTRODUCTION.

HuQAS EQA Programs.

Accredited to ISO/IEC 17043:2010 since 2009, HuQAS offers cost-effective, high-quality EQA/PT panels across 40+ programs, supported by a robust quality management system, expert technical support, and a strong culture of excellence focused on laboratory science and patient safety.

- ▶ Bacteriology
- ▶ Blood Screening
- ▶ Chemistry
- ▶ Clinical Microbiology
- ▶ Diagnostic Immunology
- ▶ Hematology
- ▶ Molecular
- ▶ Mycology
- ▶ Parasitology
- ▶ Serology
- ▶ Transfusion EQA

PROFICIENCY TESTING DESIGN



EQA PROGRAMS

Basic Chemistry - H43BCHE

4 test events 3 samples 5ml with 4 shipments

Basic Chemistry - H121BCHE

12 test events 1 samples 5ml with 2 shipments

1. Acid Phosphatase, Prostatic
2. Acid Phosphatase, Total
3. Alanine Aminotransferase (ALT/SGPT)
4. Albumin
5. Alkaline Phosphatase(ALP)
6. Amylase, Total
7. Amylase , Pancreatic
8. Aspartate Aminotransferase(AST/GOT)
9. Bilirubin, Direct
10. Bilirubin, Total
11. Calcium
12. Chloride
13. Creatine Kinase
14. Creatinine
15. Gamma Glutamyltransferase(GGT)
16. Glucose
17. Iron
18. Lactate
19. Lactate Dehydrogenase(LDH)

20. Lipase
21. Lithium
22. Magnesium
23. Phosphorous
24. Potassium
25. Protein Total
26. Sodium
27. Urea/Urea Nitrogen
28. Uric Acid
29. Zinc

Lipids

1. Cholesterol, HDL
2. Cholesterol, LDL
3. Cholesterol Total
4. Triglycerides

Report Only Available | Sample Type: Lyophilized.

Special Chemistry - H32SPCH

3 test events 2 samples 3ml with 3 shipments

1. Alpha Fetoprotein
2. Beta - hcg
3. Carcinoembryonic Antigen
4. C-Peptide
5. DHEA - Sulphate
6. Dogoxin
7. Estradiol
8. Estriol, Total
9. Estriol, Unconjugated
10. Ferritin
11. Folate
12. Follicle Stimulating Hormone(FSH)
13. Human Growth Hormone
14. Immunoglobulin
15. Insulin

16. Luteinizing Hormone (LH)
17. Progesterone
18. Prolactin
19. Prostate-specific Antigen (PSA), total
20. Prostate-specific Antigen (PSA), free
21. Testosterone
22. Thyroid Stimulating Hormone(TSH)
23. Thyroxine, Free(FT4)
24. Thyroxine, Total(TT4)
25. Triiodothyronine Total(TT3)
26. Triiodothyronine Total(FT3)

Report Only Available | Sample Type: Lyophilized Serum.

Urinalysis - H32URIN

3 test events 2 ^{*} samples 5ml with 3 shipments

1. Bilirubin
2. Ketones
3. Protein
4. Bilirubin - confirmatory
5. Leukocyte esterase
6. Reducing Substances
7. Glucose
8. Nitrite

9. Specific Gravity
10. Human Chorionic Gonadotropin(HCG)
11. Osmolality
12. Urobilinogen
13. Hemoglobin
14. pH

Report Only Available | Sample Type: Urine.

Tumor Markers - H32TUMK

3 test events 2 samples 2ml with 3 shipments

1. Cancer Antigen 72 - 4(CA 72 - 4)
2. Prostate-specific Antigen Free(PSA)
3. Alpha-fetoprotein
4. Carcinoembryonic Antigen (CEA)
5. Cancer Antigen 125 (CA 125)

6. Cancer Antigen 15 - 3 (CA 15 - 3)
7. Prostate-specific Antigen Total
8. Ferritin
9. Cancer Antigen 19 - 9 (CA 19 - 9)
10. B - hCG
11. Cancer Antigen 27.29 (CA 27.29)

Report Only Available | Sample Type: Lyophilized Serum.

EQA PROGRAMS

Coagulation - H33COAG	3 test events 3 samples 1ml with 3 shipments
1. Activated Partial Thromboplastin Time Floribinogen 2. Prothrombin Time (PT) (APTT) 3. International Normal Ratio (INR) 4. Thrombin 5. Anti - thrombin III	Report Only Available Sample Type: Lypholised Plasma.
Basic Hematology H122HEMA	12 test events 2 samples 1ml with 2 shipments
1. Hematocrit 2. Mean Copuscular Volume (MVC) 3. WBC Differential (Lymphocytes,monocytes) 4. Mean Copuscular Hemoglobin (MCH) 5. Red Blood Cell Count 6. White Blood Cell Count 7. Mean Copuscular Hemoglobin Concentration(MCHC) 8. Red Cell Distribution Width 9. Hemoglobin 10. Platelets	Report Only Available Sample Type: Whole Blood.
Hematology 5-part Differential - (H43HEFA, H43HEFB, H43HEFE, H43HEFG, H43HEFH)	4 test events 3 samples 1ml with 4 shipments
1. Hematocrit 2. Mean Copuscular Volume (MVC) 3. WBC Differential (Lymphocytes, Monocytes, Basophils, Neutrophils, Eosinophils) 4. Mean Copuscular Hemoglobin (MCH) 5. Red Blood Cell Count 6. White Blood Cell Count 7. Mean Copuscular Hemoglobin Concentration(MCHC) 8. Red Cell Distribution Width 9. Hemoglobin 10. Platelets	Report Only Available Sample Type: Whole Blood.
Hematology 3-part Differential - H43HETA	4 test events 3 samples 1ml with 4 shipments
1. Hematocrit 2. Mean Copuscular Volume (MVC) 3. WBC Differential (Granulocytes, Lymphocytes, Monocytes) 4. Mean Copuscular Hemoglobin (MCH) 5. Red Blood Cell Count 6. White Blood Cell Count 7. Mean Copuscular Hemoglobin Concentration(MCHC) 8. Red Cell Distribution Width 9. Hemoglobin 10. Platelets	Report Only Available Sample Type: Whole Blood.
Basic Glycated Hemoglobin - H32BGHG	3 test events 2 samples 1ml with 3 shipments
1. HBA1C 2. Hemoglobin	Report Only Available Sample Type: Lyophilised.
Lymphocyte Immunophenotyping - H32LIPH	3 test events 2 samples 1ml with 3 shipments
1. Cd3 (T cells) 2. Cd4 (T Helper) 3. Cd4% 4. Cd3 (T Cytotoxic) 5. Cd8+ 6. Cd8%	Report Only Available Sample Type: Whole Blood.

EQA PROGRAMS

Sickle Cell Screening - H32SCSC	3 test events 2 samples 2.5ml with 3 shipments
1. Sickel Cell Screening	Report Only Available Sample Type: Whole Blood.
Blood Gas - H43BGAS	4 test events 3 samples 2.5ml with 3 shipments
1. pH 2. pCO ₂ 3. pO ₂ 4. Na ⁺ 5. K ⁺	6. Ca ⁺⁺ 7. Mg ⁺⁺ 8. Cl ⁻ 9. Glucose 10. Lactate Report Only Available Sample Type: Am poule .
Peripheral Blood Film Slides - H32PBFS	3 test events 2 slides with 3 shipments
1. Red Cell Morphology 2. Differential Of Normal and Abnormal White Blood Cells 3. Platelet Count 4. Platelet Morphology	Report Only Available Sample Type: Fixed Blood Slides.
Basic Transfusion Medicine - H43BTME	4 test events 3 samples 1ml with 4 shipments
1. Foward Blood Grouping 2. Reverse Blood Grouping 3. Cross Matching	Report Only Available Sample Type: Packed Cells Plasma
Syphilis Serology - H43TREP	4 test events 3 samples 1ml with 4 shipments
1. Anti-Treponema 2. None Treponemal Antibodies	Report Only Available Sample Type: Serum.
Hepatitis Serology - H43HEPM	4 test events 3 samples 1ml with 3 shipments
1. Anti-HAV IgG 2. Anti-HAV IgM 3. Anti-HAV Total 4. Anti-HBc IgM 5. Anti-HBc Total 6. Anti-HBe	7. Anti-HBs 8. Anti-HCv 9. HBesAg 10. HBsAg 11. HCV Ag Report Only Available Sample Type: Serum.
Occult Blood - H33OCCB	3 test events 3 samples 1.5ml with 4 shipments
1. Occult Blood Test	Report Only Available Sample Type: Stool Sample.
SARS-CoV-2 Molecular - H32COVA	3 test events 2 samples 0.75ml with 3 shipments
1. SARS-CoV-2 Nucleocapsid Antigen 2. SARS-CoV-2 Detection	Report Only Available Sample Type: Liquid.
SARS-CoV-2 Molecular - H33COVD	3 test events 3 samples pellets with 3 shipments
1. SARS-CoV-2 Detection 2. SARS-CoV-2 Molecular Gene Identification	Report Only Available Sample Type: Pellets.

EQA PROGRAMS

HIV Screening - H43HIVA	4 test events 3 samples 1ml with 4 shipments
1. Anti-HIV-1 2. Anti-HIV-1/2 3. Anti-HIV-2	Report Only Available Sample Type: Plasma.
HBV DNA Viral Load - H43HBVL	4 test events 3 samples 1.5ml with 4 shipments
1. HBV DNA	Report Only Available Sample Type: Frozen Human Plasma
HCV RNA Viral Load - H43HCVL	4 test events 3 samples 1.5ml with 4 shipments
1. HCV RNA	Report Only Available Sample Type: Frozen Human Plasma.
HIV Viral Load - H43HBVL	4 test events 3 samples 1.5ml with 4 shipments
1. HIV -1 RNA	Report Only Available Sample Type: Frozen Human Plasma
Early Infant Diagnosis - H42HEID	4 test events 3 samples with 4 shipments
1. Early Infant Diagnosis Test	Sample Type: DBS (Dry Blood Spot)
Rifampicin - Resistant Mycobacterium Tuberculosis- H33RRTB	3 test events 3 samples with 3 shipments
1. Mycobacterium Tuberculosis Detection 2. Mycobacterium Tuberculosis Rifampicin Resistance	Sample Type: Pellets.
Mycobacterium Acid Fast Stain - H43MAFS	4 test events 3 slides with 4 shipments
1. AAFB Detection 2. AAFB Quantification	Report Only Available Sample Type: Fixed Glass Slides
TB Lipoarabinomannan (LAM) Test - H33TBLM	3 test events 3 slides with 3 shipments
1. TB LAM	Sample Type: Urine
Gram Stain - H43GRAM	4 test events 3 slides 4 shipments
1. Gram Stain Reaction 2. Gram Stian Morphology	Report Only Available Sample Type: Fixed Glass Slides.
Bacterial Identification - H43BACT	4 test events 3 swabs with 4 shipments
1. Bacterial Identification 2. Gram Stain 3. Antimicrobial Susceptibility Testing (AST)	Sample Type: Swabs.

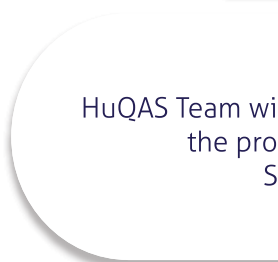
EQA PROGRAMS

Urine Culture - H43URIC	4 test events 3 samples with 4 shipments
1. Bacterial Identification 2. Gram Stain 3. Antimicrobial Susceptibility Testing (AST)	Sample Type: Swabs.
Cryptococcus Antigen - H32CRYA	3 test events 2 samples 1ml with 3 shipments
1. Cryptococcus Neoforamans	Sample Type: Serum
KOH Slides - H32KOHs	3 test events 2 slides 3 shipments
1. Fungal Identification	Sample Type: Fixed Glass Slides.
Helicobacter Pylori Antigen - H33HPAG	3 test events 3 samples with 3 shipments
1. H. Pylori Antigen	Sample Type: Stool.
Malaria - H43MALA	4 test events 3 slides with 4 shipments
1. Malaria Parasites Detection 2. Malaria Species Identification and Quantification 3. Malaria Species Stage Identification	Report Only Available Sample Type: Fixed Blood Slides.
Malaria Rapid Diagnostic Test - H43MRDT	4 test events 3 samples 1ml with 4 shipments
1. Malaria Parasites Detection 2. Malaria Antigen	Sample Type: Whole Blood Samples.

REGISTRATION PROCESS



Identify Program(s) of interest from the Catalogue.
Fill the Order Form and email to
info@huqas.org | huqas@huqas.org.



HuQAS Team will get intouch with a Quote of the program(s) selected and Standard Terms.



Once Payment is done. HuQAS shall train the laboratory team on the HuQAS Informatics System.

REPORT ONLY | SAMPLE ONLY SUBSCRIPTIONS | OFF – CYCLE | VALIDATION SUBSCRIPTION

1. Report Only – Report 2nd Set of results using the same samples at no extra cost for the following programs:
 - Basic Chemistry
 - Special Chemistry
 - Hematology 3 – Part Differential
 - Urinalysis
 - Hematology 5 – Part Differential (no differentials)
2. Sample Only – Receive a 2nd sample set (without evaluation/reports) for 70% of Program Price. Available for all programs.
3. Off – Cycle Subscription – This is a standalone subscription for EQA program price. You receive one set of samples for a just concluded Test Event and Assigned for the price of normal EQA program.
4. Validation Subscription – Validated Samples with an associated report of survey values, but do not submit results for evaluation. You receive one set of survey validated samples with an associated report of survey values, but do not submit results for evaluation.
5. To order these types of subscriptions, please write the subscription type on the Order Form and send it to mail: huqas@huqas.org

By placing your order, you agree to these terms.

1. Contact HuQAS for current program prices at hugas@hugas.org. Payment can be made in US Dollars or equivalent Kenya Shillings at the time of payment.
2. For participants outside Kenya, prices exclude any applicable taxes charged by individual Government.
3. Prices include shipping and handling for orders within Kenya. All other orders are subject to additional shipping charges from Nairobi.
4. We will replace at our cost any test samples broken or compromised during shipping.
5. Test samples broken or compromised after your receipt will be replaced at your cost (current program price pro-rated by event cycles).
6. The payment is due on the order confirmation. Shipments will be made only upon receipt of payment. Overdue accounts bear interest at 1.5% per month, compounded on a monthly basis.
7. Shipments and/or performance information may be withheld for overdue accounts.
8. We reserve the right to or not offer programs with less than ten (10) participants by providing note and a full refund.
9. Collusion with other participants is strictly prohibited and we reserve the right to withdraw your participation on the evidence of this malpractice.
10. Test Samples may contain pathogenic materials; you assume all risks and responsibilities for the receipt, handling, storage, use, and disposal of EQA material.
11. Performance information will only be disclosed to regulatory bodies upon your written permission.
12. HuQAS may from time-to-time subcontract sourcing, evaluation of some PT samples, and shipping services. When subcontracting occurs, it is placed with a competent subcontractor and the proficiency testing provider is responsible for this.
13. By signing the standard terms, you give HuQAS (Human Quality Assessment Services) permission to collect, process, and store your organizational and personnel data for External Quality Assessment, Know Your Customer (KYC) verification, scientific research, and to ensure compliance with applicable laws and regulations.

CLIENT AUTHORIZATION

Name:	Company / Institution Stamp
Position/Title	
Signature:	
Date:	
Payment amount from preceding page(s):	
Local Purchase Order Number:	

HUMAN QUALITY ASSESSMENT SERVICES

Name	Stamp
Position/Title	
Signature	
Date	

EQA POLICIES

1.SHIPMENTS

Two weeks prior to a PT shipment, the person designated as shipping contact will receive an <Advance Shipment Notice> through their registered email address.

The Advance shipment notice v information on programs to be received and demographic information of the lab together with all the information relative to methods, reagents and instruments that you have provided to HuQAS.

Any and all changes of Shipment dates shall be communicated in advance to all affected participating laboratories

Any and all changes of shipment dates shall be communicated in advance to all affected participating Laboratories Shipment dates of the samples cannot be changed.

Extensions or excused status will not be granted due to routing/receiving problems within an institution causing non-delivery of samples.

Programs may be ordered at any time and the price is prorated to the number of remaining test events. All samples are shipped for delivery within 2 working days. If samples are not received within 24 hrs of shipping contact HuQAS Support for tracking.

2.ORDERS

Changes to purchased programs should be directed to HuQAS via email. Changes to programs are dependant on availability of product.

All communication should include:

- *Your PT ID.
- *Laboratory name, address, email and telephone number.
- *Contact name.
- *Information on programs added or cancelled.
- *Billing information.

All prices will be prorated by the number of test events/year.

3.SAMPLES

All shipments should immediately be opened upon receipt and contents checked for the following:

- *Damaged samples
- *Missing samples
- *Incorrect samples

For replacements, contact HuQAS support. Store samples at the appropriate temperature and follow all sample handling protocols indicated in the "Handling & Reporting Instructions"

All PT samples should be considered as potentially hazardous and laboratories should follow their protocols for handling biohazard materials when processing or discarding samples. PT samples should be analyzed as soon as possible and results submitted to HuQAS.

4.RESULTS SUBMISSION.

DO NOT MAIL RESULTS TO HuQAS

Participants will receive a reminder 2 days prior to the Results Deadline that their results are due. Late results will not be evaluated.

5.PT PERFORMANCE

All results are accessible in the HuQAS informatics approximately 10 working days of the Results Deadline. Reports consist of:

- *Program performance report – all analyte results performance in a given test event.
- *Alert report (if applicable) - highlights analytes/vials that did not meet “acceptable criteria”.

6.CORRECTIONS

PT Performance reports may also be sent to accrediting | regulatory agencies upon a laboratory’s written request. Therefore it is critical that you review your reports immediately and report any errors on our part to HuQAS support.

A corrected report will be sent to you as soon as possible. Appeals for report can only be done within 7 days after release of the report. Any appeals that are made shall be reviewed and responded on email.

Errors on the part of the lab, e.g., results entered from incorrect instrument, wrong units or incorrect order will not be corrected.

7.PT FAILURES

Before contacting HuQAS Support, participants should follow their protocols for troubleshooting samples, instrument or reagent problems. HuQAS Support can provide suggestions and other resources to assist participants. Samples for remedial PT are available on a limited basis but there is a cost associated with the samples.

8.REPORTS

It is the responsibility of the participant to keep all records of participation in proficiency testing.

Participants can access all reports and graphs including archived reports for the past two years from “REPORTS” section online at www.eqa.huqas.org. or for monthly EQA on www.monthly-eqa.huqas.org

All HuQAS reports issued to participants are authorized for release by the Chief Executive Officer or his/her designee.

All HuQAS reports either Interim or Final or Amended Reports.

Participants reports are confidential unless a lab waives confidentiality in writing.

The contents of PT samples are clearly indicated in the handling and storage instructions which accompany every shipment and can also be downloaded on every laboratory dashboard account.

Participants data evaluation is based on consensus mean which is determined by participants in a specific peer group. For details on evaluation please refer to the evaluation criteria.

9.ACCREDITATION AGENCIES AND REPORTS

Participation in an approved PT program is part of your laboratory's Quality Assurance requirements.

Reports may be sent to laboratory oversight bodies | regulatory agencies upon written permission. As an approved PT provider we will report PT results in a manner that meets the laboratory oversight bodies | regulatory agencies requirements.

It is the responsibility of the participating laboratory to notify HuQAS Support which agencies should receive PT performance reports.

CONTACTS

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Nairobi, Kenya

Website: www.huqas.org

Email : huqas@huqas.org

Phone: +254-020-3542483

HuQAS EVALUATION CRITERIA

“.....advancing healthcare through improved laboratory testing”

This report interpretation guide aims to explain the laboratory reports and statistical evaluations to participants, providing detailed yet easy-to-read information on laboratory performance to assess the level of quality and identify areas for improvement.

HuQAS reports are designed with a user-friendly, easy to interpret per analyte format that includes a summary performance report, that includes your laboratories Overall Score per program allowing for effortless interpretation of analytical performance.

The HuQAS report not only offer a comparison of laboratory results with other laboratories using the same analytical instrument, method, or all method but also provide detailed information for comparison to other analytical instruments, and methods.

The inclusion of statistical breakdowns by all methods, your method, and, where applicable, your instrument with Robust Mean, CV, and SD to further enhance the value of your reports.

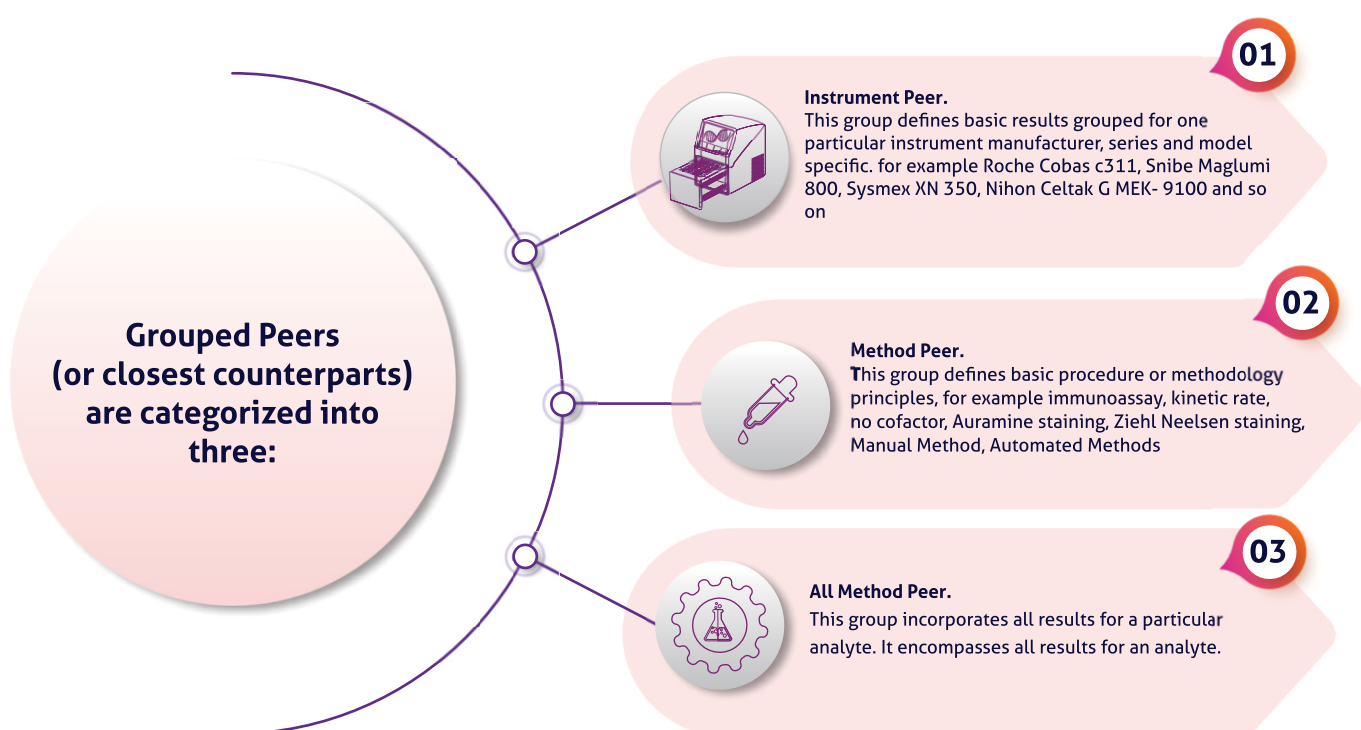
Quantitative Analytes

In accordance with ISO 13528:2015, participating laboratories are evaluated based on their deviation from a consensus performance of clustered peers (or closest counterparts).

A numerical criterion is utilized to determine if the deviation constitutes a matter of concern.

Participants with a significant deviation (large z-score with positive or negative deviation) from the mean are considered outliers and receive a "NOT ACCEPTABLE" grade. An outlier refers to a value within a dataset that is inconsistent with other values in the same set.

PEER GROUPING CATEGORISATION



QUANTITATIVE LABORATORY REPORT

HUQ0001 | Basic Chemistry | Report No: 509-2-120913

C Albumin [g/L]

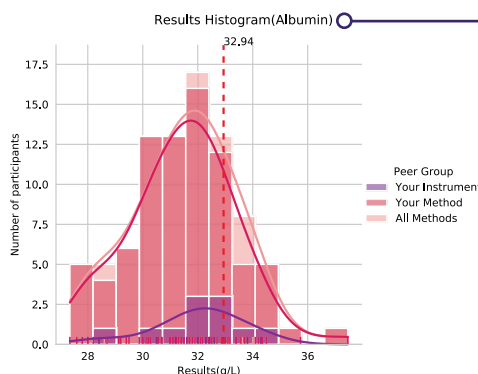
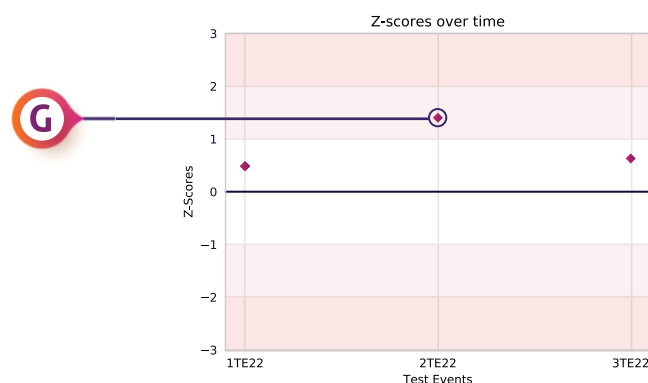
B Score: 100%

D	Instrument Model:	Method:	Peering by:
	Roche Integra 400/Plus	Bromocresol Green	Bromocresol Green (METHOD)

Albumin - Sample A

E	Result	N	Mean	SD	SE	CV(%)	Z-Score	Grade
	32.94	228	31.49	2.31	0.31	7.34	0.63	ACCEPTABLE

F	Peer Group Name	N	Mean	SD	SE	CV%
	ALL	507	31.57	2.34	0.30	7.40
	Human HumaStar 100 (I)	187	30.71	2.02	0.59	6.57
	Roche Cobas c111 (I)	75	33.13	2.7	0.94	8.16
	Roche Integra 400/Plus (I)	52	32.13	1.6	0.60	4.97
	Human HumaStar 200 (I)	8	31.64	2.2	0.97	6.96



A Your Lab Code (HUQ001), the Program Name (Basic Chemistry), a unique report number that bears the test event number (509), the program ID (2) and a unique analysis report number (120913)

B An average percentage score based on the number of samples.

C Your Analyte report in your labs units of entry

D Your analyte and Your method used in results entry, and the peer group your results are represented by on section E.

E **Results:** Your Result (X_i) in your units of entry,

N: Number of Participants for the analyte,

Mean: Robust Average (X_{pt}) of all participant results.

SD / σ_{pt} : Standard deviation for proficiency assessment (σ_{pt}) calculated from participants results.

S.E or U_m : Uncertainty associated with Standard Deviation of the results.

$$S.E \text{ or } U_m = \frac{1.25 \times \sigma_{pt}}{\sqrt{p}}$$

C.V: Coefficient of Variation calculated as:
 $CV = \sigma_{pt} / X_i - 100$

Z Score: measure of how many standard deviations below or above the mean a data point is.

$$Z \text{ Score} = \frac{X_{pt} - X_i}{\sigma_{pt}}$$

F **Grade For a:**
 z - score between $|z| \leq \pm 2.0$ is **ACCEPTABLE**
 z - score between $\pm 2.0 < |z| < \pm 3.0$ is a **WARNING SIGNAL**
 z - score between $|z| \geq \pm 3.0$ is **NOT ACCEPTABLE**

A performance comparison of other methods used to analyse the analyte. You can compare the Robust mean (X_{pt}), the SD (σ_{pt}), the uncertainty (of the calculated robust mean, the CV and the number of participating laboratories and results for each peer group.

G Z - Score plot over time for lab test quality control can help laboratories detect issues early, monitor their performance, and ensure consistent, accurate results.

H Overlapping histograms provides a clear visual representation of data distribution and facilitates identification of trends, outliers, and potential issues.

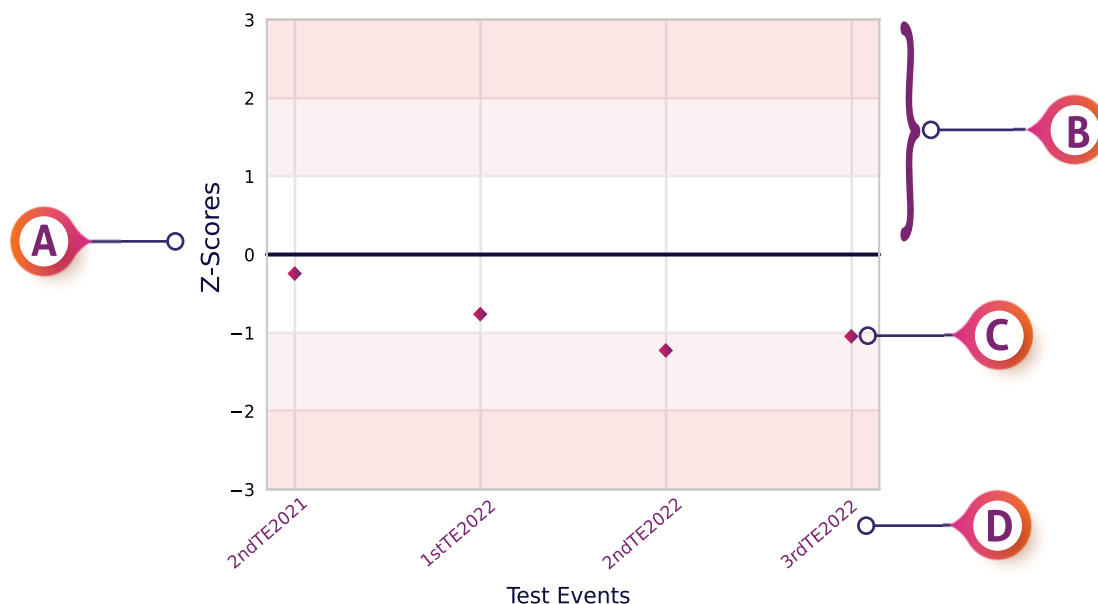
Its useful for comparison of performance among different laboratories, methods, or instruments facilitating benchmarking and identification of best practices.

QUANTITATIVE LABORATORY REPORT

The Z - Score Plot combines performance scores over several rounds of a proficiency testing scheme.

It allows trends analysis, and other features of the results, to be identified that are not apparent when performance scores for each round are examined separately.

Anatomy of Z - Score Over - time Plot



A Z - Score is plotted for each sample, for monthly you will receive a plot for every month of result entry. For Quarterly you will receive a plot for every analyte overtime.

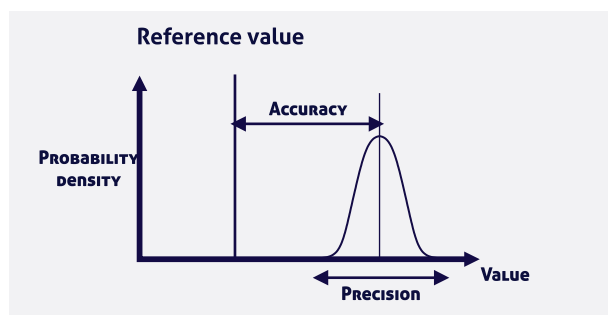
C Z - Score for each event sample, current and previous events upto 12 events for monthly and 5 events for quarterly.

B Acceptable scores (0 - 1) having no shading, Warning scores (1 - 2) having light red shading, Not Acceptable (2 - 3) have dark red shading.

D Test Events participated only, If your lab result was not entered there will be no entry for that test event.

The Overlapping histogram shows where your result is in comparison with others in the three peers groupings of All Method, Method and Instrument Peer. (ISO 13528:2015 Clause 10.2)

- A The histogram is created using actual participant results, as indicated at the X - Axis represented by singular points on the X - Axis.
- A kernel density estimate (KDE) is plotted to provide a smooth curve describing the general shape of all lab results for the analyte distribution. (ISO 13528:2015 Clause 10.3)



Accuracy is how close a your result is to the robust mean,

while

Precision is how close your result is to your peers.

Peer Group

- Your Instrument
- Your Method
- All Methods

Number of participants

Results(g/dL)

5.30 g/dL

A

B

C

D

E

F

G

H

- A** Your result represented in your units. Your result is indicated by **Red Broken Line**.
 - B** Your Instrument peer will be colored in a Light Purple, Your Method Peer will be in Red and the All Method Peer will be in light red.
 - C** Kernel Density Curve for All Method Peer
 - D** Kernel Density Curve for Your Method Specific Peer
 - E** Kernel Density Curve for Your Instrument Peer
 - F** Spread of results entered for the particular analyte.
 - G** 450 laboratories reported values between 5.25 and 5.50 in your **method peer**.
 - H** 55 laboratories reported values between 5.25 and 5.50 in your **instrument peer**.

QUALITATIVE LABORATORY REPORT

Qualitative Analytes

Qualitative analytes are those whose results are expressed as **categorical outcomes**, rather than numerical values. These may include responses such as:

- * Positive / Negative
- * + / ++ / +++
- * MPS seen / No MPS seen
- * Stage / Not Applicable, and other similar qualitative indicators.

Assigned values for these analytes are typically determined through consensus results from expert or reference laboratories, or from validated reference materials.

Participant results are evaluated based on their agreement with the assigned value:

- * **AGREEMENT** with the assigned value is graded as **ACCEPTABLE**.
- * **DISAGREEMENT** with the assigned value is graded as **NOT ACCEPTABLE**.

HUQ0000|3rdTE2020(FINAL)|Hepatitis Serology|Report No:509-10-128587

Anti-HAV -IgM

Instrument Model:	Method:	Reagents:
Manual Determination	Double Antigen lateral flow chromatographic Immunoassay	CTK Biotech Onsite HAV-IgM/IgG CAT R0090C

Sample	N	Responses	Acceptable Responses	Grade
A	98	Non Reactive	Non Reactive	ACCEPTABLE
B	98	Reactive	Reactive	ACCEPTABLE
C	98	Non Reactive	Non Reactive	ACCEPTABLE

Your Score: 100%

Anti-HAV-IgM 3rd Event 2020

Reagents/ Kits Performance Comparison

Reagents	N	Acc. (%)	Not Acc. (%)
CTK Biotech Onsite HAV-IgM/IgG CAT R0090C	56	100.0	0.0
BioMerieux Vidas HAV IgM CAT #30307	24	100.0	0.0
Maglumi Anti-HAV CAT# 130210007M/ 130610007M	12	50.0	0.0
Autobio HAV IgM CLIA Microparticles CAT# CMC0701/702/703/704/705	10	100.0	0.0
Abbott AxSYM HAVAB-M 2.0	1	100.0	0.0
Vaxpert HAV IgM CAT#IHA-302	1	100.0	0.0

QUALITATIVE LABORATORY REPORT

- A** Indicates a unique laboratory code (*HUQ000*), Test Event Name (*3rdTE2020*), Program Name (*Hepatitis Serology*), Unique per analysis Report Number (*509-10-128587*) and Report Status (*Interim, Final or Amended*).
- B** An Average percentage score based on ACCEPTABLE, WARNING and NOT ACCEPTABLE.
- C** Simple way to evaluate the performance of other kits, instrument, methods used to analyze the parameter.
- D** Bar graph indicating a quick visualization of how the lab result compared performance to other laboratories per analyte.
- E** Description of analyte performance against assigned grade (Acceptable, Not Acceptable). Indicating expected responses along with your lab responses and the overall "N" number of participants.
- F** Outlines your laboratory's Instrument models, Methods and Kits/Reagents, used in the results entry.
- G** An indication of the test or analyte analysed by the lab.

SEMI- QUALITATIVE LABORATORY REPORT

HUQ0000| 3rdTE2024 (FINAL) | Malaria | Report No: 636-12-1589712

F Malaria Species Identification and Quantification

Your Score: 50%

Instrument Model:	Method:	Reagent:
Manual Determination	Manual	Not Applicable

Sample	N	Responses	Acceptable Responses	Grade
A	38	Plasmodium falciparum,	Plasmodium falciparum,	ACCEPTABLE
E Quantification		223	lower.L	NOT ACCEPTABLE
			target	
B	38	Plasmodium malariae,	Plasmodium vivax,	NOT ACCEPTABLE
C	38	Plasmodium malariae, Plasmodium falciparum,	Plasmodium malariae, Plasmodium falciparum,	ACCEPTABLE

- A** Indicates a unique laboratory code (*HUQ000*), Test Event Name (*3rdTE2024*), Program Name (*Malaria*), Unique per analysis Report Number (*636-12-1589712*) and Report Status (*Interim, Final or Amended*).
- B** An Average percentage score based on ACCEPTABLE, WARNING and NOT ACCEPTABLE.
- C** Outlines your laboratory's Instrument models, Methods and Kits/Reagents, used in the results entry.
- D** Description of analyte performance against assigned grade (Acceptable, Not Acceptable). Indicating expected responses along with your lab responses and the overall "N" number of participants.
- E** Quantification summary performance on your laboratories that is scored against expected ranges in accordance to WHO guidelines.
- F** An indication of the test or analyte analysed by the lab.

REPORT INTERPRETATION AND PROTOCOL STATEMENTS

1) Sample Preparation

Proficiency testing (PT) panels' raw materials were sourced, transported, and handled in accordance with international and national regulatory and ethical requirements, as outlined in the PT operational procedure (HuQAS/QP/0008) and the WHO Guidelines for Safe Transport of Infectious Substances and Diagnostic Specimens (WHO/EMC/97.3).

Sample preparation and characterization are conducted at the HuQAS PT Laboratory in accordance with the PT operational procedure (HuQAS/QP/0008) and the WHO Manual for the Organization of External Quality Assessment in Health Laboratories (WHO-DIL-LAB-99)

2) Homogeneity and Stability Testing

The PT panels provided have well-defined homogeneity and stability reports. Homogeneity and stability testing are performed in accordance with ISO 13528:2022 and the procedure for homogeneity and stability testing (HuQAS/QP/0014)

3) Assigned Values, Metrological Traceability, and Measurement Uncertainty

Assigned values, their associated metrological traceability, and measurement uncertainty for each program are established per the procedure for assigning values (HuQAS/QP/0015) and based on ISO 13528:2022.

- * PT materials and their assigned values are metrologically traceable to measurement reference methods. This traceability is documented in the raw materials assay sheets and supported by robust statistical methods detailed in ISO 13528:2022
- * Measurement uncertainty for quantitative programs is estimated using robust statistical methods as outlined in the procedure for data management (HuQAS/QP/0013), in line with ISO 13528:2022

4) PT Design and Implementation

The PT scheme is conducted quarterly, with three testing cycles per year. Details regarding PT design and implementation are outlined in the PT operational procedure (HuQAS/QP/0008) and the catalogue (HuQAS/A0/0002).

5) Statistics

In accordance with **ISO 13528:2022**, HuQAS reports provide the following statistical parameters for interpreting results:

1. Z-Score ($|Z|$):

- * $|Z| \leq 2.0$: Acceptable.
- * $2.0 < |Z| < 3.0$: Warning signal.
- * $|Z| \geq 3.0$: Not acceptable.
- * An asterisk (*) next to the Z-Score indicates evaluations were calculated using Z-prime (Z'), as detailed in ISO 13528:2015 Clause 9.5.

2. Standard Error (SE):

- * An estimate of the measurement uncertainty for the assigned value.
- * Acceptability criteria are outlined in the catalogue.

3. Coefficient of Variation (CV):

- * An estimate of the overall variability of participants' results, expressed as the ratio of the standard deviation to the mean.
- * Acceptability criteria are outlined in the catalogue.

6) Method of Assigning Values

In accordance with **ISO 13528:2022**, HuQAS assigns values for PT materials using one or more of the following ISO-recognized approaches:

1. Consensus Values from Participants

This is the primary and most commonly used method for assigning target values. Participants are grouped into **peer groups** based on similar technology, method, or instrument platform. When a peer group has **five (5) or more** participants, the assigned value is calculated using **robust statistical methods** applied to the results of that group. The resulting robust mean becomes the assigned (target) value.

2. Certified Reference Materials

where CRM have been used, values provided by the manufacturer will be adopted directly to assign target to respective programs.

3. Use of reference measurement procedure

EQA samples that are not CRM will be evaluated in the HuQAS laboratory using reference methods. The results will be compared with the certificate of analysis provided by the manufacturer to assign target values

4. Consensus Values from Expert Laboratories and Experts

EQA materials that are not CRM will be referred to selected laboratories or expert consultants for evaluation. A consensus of the results will be used to assign target values using robust statistics. This will be done for analytes that cannot be evaluated internally in the HuQAS laboratory.

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PERFORMING ROOT CAUSE ANALYSIS

Continuous Testing, Continuous Improvement

The term external quality assessment (EQA) is used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory. This comparison can be made to the performance of a peer group of laboratories or to the performance of a reference laboratory.

Your External Quality Assurance (EQA) performance report will help you understand the quality of your lab's test results. EQA should be done in addition to internal quality controls (QC).

EQA allows you to see how your lab is performing compared to a group of your peers.

All results on your EQA performance report should be examined for not acceptable Results and warning signals, unusual trends like positive or negative bias, sudden shifts, or other problems. Not acceptable EQA results can arise from both systematic and random sources of error.

Systematic Errors refers to errors which are present for every measurement of a given sample. Narrow down on results on one side of the target value and where a bias is seen using the Z-Score values.

For example all of your EQA results are above or below the peer group mean.



Systematic Errors affect the accuracy of your results.

Random Error refers to the spread in the values of EQA results from one measurement of the quantity to the next as is shown by results that are on average close to the target value but there are a few exceptions that show large deviations from the target value.



Random Errors affect the precision of your results.

How to Investigate Not Acceptable Result(s).

Laboratory results and Comparative Group data lists the information that would indicate if the EQA result is satisfactory or not and also how it compares to other labs.

Sample	Result (mmol/L)	Result Code	z-Score	Grade / Comment
A	1.6	OK	-0.44	ACCEPTABLE
B	1.6	OK	0.5	ACCEPTABLE
C	1.55	OK	0.26	ACCEPTABLE
D	1.6	OK	-0.46	ACCEPTABLE
E	2.74	OK	-0.23	ACCEPTABLE

COMPARATIVE GROUP DATA IN (mmol/L)				
St. Count	Mean	Std. Dev.	Std. Error	CV (%)
129	1.68	0.19	0.02	11.5
129	1.53	0.15	0.02	9.88
129	1.51	0.15	0.02	10.15
129	1.69	0.2	0.02	11.66
129	2.79	0.22	0.03	7.85

Score: 100%

The results that have a NOT ACCEPTABLE Grade / Comment, review the z -score value that indicates the is a measure of distance, or bias, of one result compared to the mean of results from its peer group.

To estimate and interpret the deviation of your results from the comparative group data by means of the Z - Score the HuQAS reports use the following criteria:

Z-score Interpretation: $|Z| \leq \pm 2.0$ is ACCEPTABLE, $\pm 2.0 < |Z| < \pm 3.0$ is a WARNING SIGNAL, $|Z| \geq \pm 3.0$ is NOT ACCEPTABLE

Where $|Z|$ indicating the range of Z - SCORE that your parameter results has obtained.

To review how one performed in reference to others, the data under Comparative Group Data would be helpful

The acceptable range is determined by the evaluation criteria for that analyte
For example if the evaluation criteria is Peer Group Mean $\pm$ 2SD then the target value (peer group mean) is determined from the results submitted in that peer group, after outliers have been removed. We would then (+) add and (-) subtract 2 Standard Deviations from the mean to get the upper and lower limits of the acceptable range

The peer group is ideally a group of labs that are all using the same instrument and reagent for
The peer group is ideally a group of labs that are all using the same instrument and reagent for results Indicated by Peered By: <.....>

Depending on the test program, a result could be evaluated against the peer group mean or a pre-determined reference value.

Possible Causes of Errors to cause Not Acceptable Grade(s).

Random Errors

- * Insufficient mixing of sample, especially following freezing and for samples requiring good homogeneity (for example, hematology samples).
- * Poor pipetting
- * Transcription errors
- * Sample mix-up
- * Incorrect result unit submitted
- * Testing not performed immediately after sample vials are opened (for example, blood gases vials)
- * Incorrect submethod selected
- * Dilution-related problem (wrong dilution factor used, result not corrected for dilution factor, incorrect calculation)
- * Online result entry errors ('typo')
- * Suspected/known imprecision problem with test
- * Calculation (manual and automatic) errors
- * Result unit conversion not done or done incorrectly
- * Cross-contamination or carryover
- * Mis-graded/Mis-interpreted result
- * Mis-labelled sample in sampling rack

Systematic Errors

- * Inaccurate reconstitution (wrong diluent, inaccurate diluent amount, inadequate equilibration of reconstituted material)
- * Reagents contaminated, expired
- * Incorrect sequence of results entered during online result entry
- * Insufficient mixing/centrifuging before testing
- * Instrument error or malfunction
- * Incorrect storage of test kits and/or reagents and/or EQA samples
- * Instrument parameters changed
- * Compromised samples during shipping
- * Ineffective or inconsistent washing
- * Temperature of samples not proper for testing (room temperature is required for some samples)
- * Calibration-related issues with instrument (not calibrated, expired calibration, suboptimal calibration results, calibration drift)
- * Contamination of equipment
- * Wrong assay used for testing sample

Quarterly EQA 2025 Calendar

* ISO 17043 ACCREDITED EQA PROGRAMS.

Four Events Calendar 2025 (Applies to Program Code H43)

H43 HuQAS 4 Test Events, 3 Samples Per Event,
4 Events for February, April, July and October 2024

Quarterly Test Event	Ordering Deadline	Sample Dispatch Date	Event Start Date	Event Deadline Date	Interim Report Release Date	Final Report Release Date
1st Event 2025	11 Nov 2024	27 Jan 2025	10 Feb 2025	22 Feb 2025	1st Mar 2025	8th Mar 2025
2nd Event 2025	13 Jan 2025	01 Apr 2025	14 Apr 2025	26 Apr 2025	3rd May 2025	10th May 2025
3rd Event 2025	14 Apr 2025	30 June 2025	14 July 2025	27 July 2025	2nd Aug 2025	9th Aug 2025
4th Event 2025	14 July 2025	22 Sept 2025	06 Oct 2025	19 Oct 2025	25th Oct 2025	1st Nov 2025

Three Events Calendar 2025 (Applies to Program Code H33, H32)

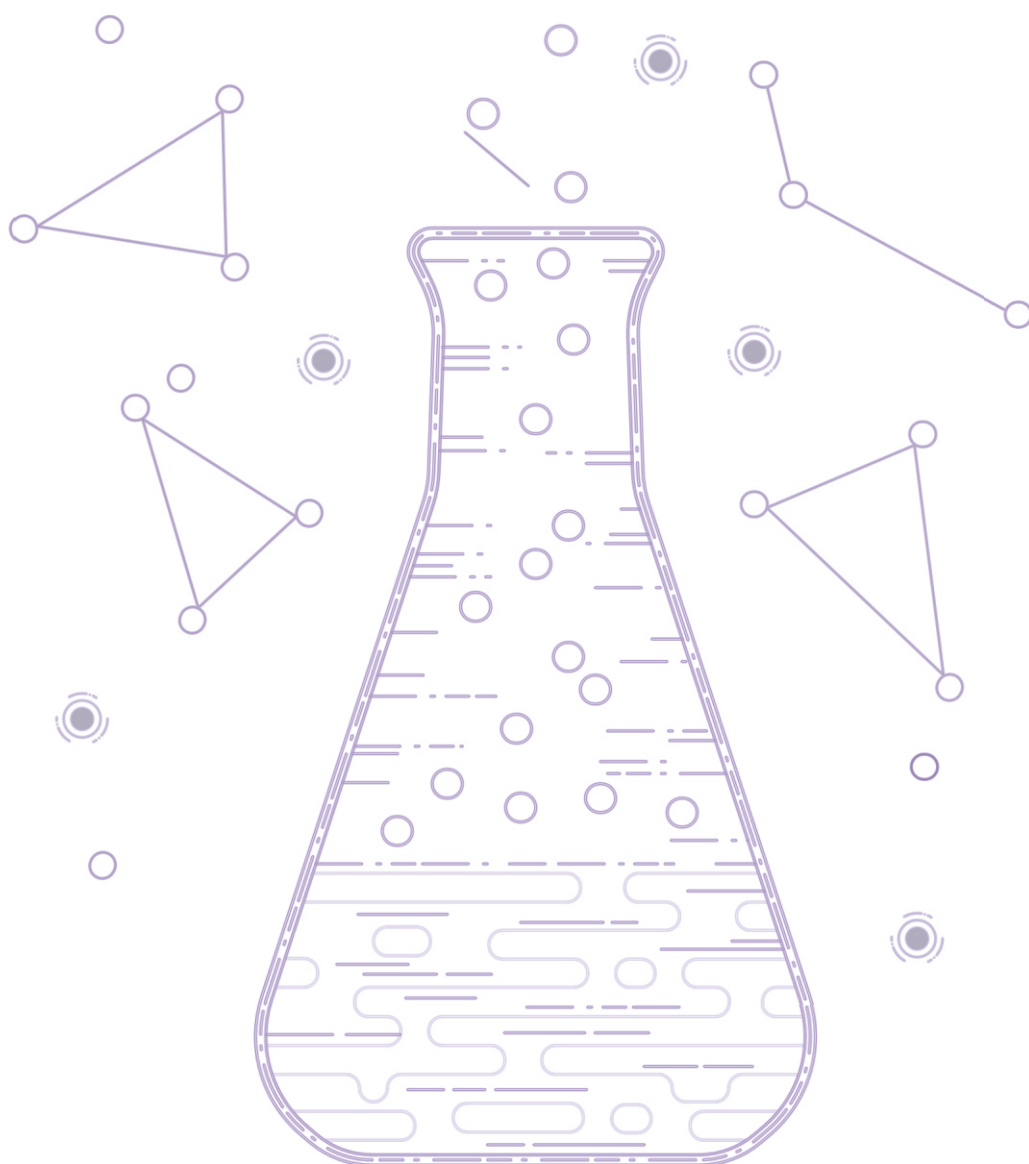
H32, H33 HuQAS 3 Test Events, 2 or 3 Samples Per Event,
3 Events for February, July and October 2024

Quarterly Test Event	Ordering Deadline	Sample Dispatch Date	Event Start Date	Event Deadline Date	Interim Report Release Date	Final Report Release Date
1st Event 2025	11 Nov 2025	27 Jan 2025	10 Feb 2025	22 Feb 2025	1st Mar 2025	8th Mar 2025
3rd Event 2025	14 Apr 2025	30 June 2025	14 July 2025	27 July 2025	2nd Aug 2025	9th Aug 2025
4th Event 2025	14 July 2025	22 Sept 2025	06 Oct 2025	19 Oct 2025	25th Oct 2025	1st Nov 2025

Monthly EQA 2025 Calendar

* JOURNEY TO QUALITY LABORATORY TESTING.

Monthly Test Event	Sample Dispatch Date	Event Start Date	Event Deadline Date	Final Report Release Date
19 Jan 2025	11 Nov 2024	19 Jan 2025	26 Jan 2025	29 Jan 2025
09 Feb 2025		09 Feb 2025	16 Feb 2025	19 Feb 2025
09 Mar 2025		09 Mar 2025	16 Mar 2025	19 Mar 2025
06 Apr 2025		06 Apr 2025	13 Apr 2025	16 Apr 2025
11 May 2025	13 Jan 2025	11 May 2025	18 May 2025	21 May 2025
15 Jun 2025		15 Jun 2025	22 Jun 2025	25 Jun 2025
13 Jul 2025		13 Jul 2025	20 Jul 2025	23 Jul 2025
17 Aug 2025		17 Aug 2025	24 Aug 2025	27 Aug 2025
14 Sep 2025	14 July 2025	14 Sep 2025	21 Sep 2025	24 Sep 2025
12 Oct 2025		12 Oct 2025	19 Oct 2025	25 Oct 2025
09 Nov 2025		09 Nov 2025	16 Nov 2025	19 Nov 2025
07 Dec 2025		07 Dec 2025	14 Dec 2025	17 Dec 2025



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