

Discrepancies in Laboratory Test Results and Their Impact on Patient Confidence in The Health System in Kirkuk, Iraq

Shenay Ahmed Mohammed¹, Ozdan Akram Ghareeb^{2*}, Yokcil Izaldeen Sowaid³

^{1,2,3} Pharmacy Techniques Department, Medical Technical Institutes/ Kirkuk, Northern Technical University, Iraq

ABSTRACT

The clinical laboratory diagnostic service is the backbone of all medical decisions, but at the health sector the results of laboratory tests for patients are becoming conflicted between various health care sectors in many regions including Kirkuk, Iraq. This diagnostic mismatch jeopardizes timely medical care, imposes a financial burden on twice on patients and significantly undermines public trust of the local health system. This study explores the causes of intra- and inter-laboratory differences, which span the diagnostic testing experience and can be broken down into pre-analytical (60-70% of errors), analytical (10-15%) and post-analytical (15-20%) phases. These inconsistencies undermine patients' trust in healthcare providers and institutions, leading them to view such issues as evidence of systemic healthcare failures. The study identifies and outlines targeted mitigation strategies through analysis of patient preparation, specimen collection and instrument calibration, and data transcription. Solving this health-care problem needs two strategies: First, laboratory staff must follow Standard Operating Procedures (SOPs) with great care, as well as strictly follow the sample rejection criteria, and apply Internal Quality Control (IQC). Second, structural governance of Directorate of Health is required: mandatory ISO 15189 accreditation, centralized External Quality Assessment (EQA) programs, unannounced audits and agreed upon provincial reference intervals are crucial to recon gain patient confidence and obtain diagnostic reliability.

ARTICLE DETAILS

Published On:
26 September 2026

Available on:
<https://ijmir.com>

KEYWORDS: Laboratory diagnostics, specimen collection, health system.

INTRODUCTION

Clinical laboratory diagnostics are the cornerstone of modern evidence-based medicine, and are likely to support up to 60% to 70% of clinical decision-making related to admission to hospital, treatment of conditions and discharge[1]. Laboratory testing is essential for the medical diagnosis, treatment, surveillance and prognosis of disease[2,3]. Although, they are essential for making a diagnosis in medicine and thus for the development of a well-defined treatment plan[4]. But, there is a significant increase in test results that contradict each other, on the same patient or sample, taken at different laboratories in the healthcare and medical laboratory sectors in some especially in developing countries [5]. This discrepancy is confusing to both physicians and patients, it postpones the delivery of proper treatment and it causes a double financial cost for the patient in terms of multiple retesting [6].

In this way, the public's faith in healthcare services weakens, sometimes forcing people to go to other governorates or other countries for diagnosis [7].

Over the last few years, the problem of the differences in the clinical laboratory results obtained at various public and private laboratories in regions of Iraq [8], including Kirkuk has become a major issue in the healthcare sector. The purpose of this study is to explore differences in laboratory test results and the reasons for their differences, to evaluate their effect on patients, and to develop systematic, standardized, solutions to these differences.

LABORATORY EXAMINATIONS CATEGORIZE

1-Microbiology: Identify pathogenic microorganisms – using direct microscopy, gram staining, culture method and Antimicrobial Susceptibility Testing (AST) – bacteria, fungi, parasites and viruses. These tests help to direct specific antibiotic treatment[9].

Discrepancies in Laboratory Test Results and Their Impact on Patient Confidence in The Health System in Kirkuk, Iraq

2- **Serology and immunology**: concerned with the study of antigens/antibodies in blood serum. Applications include the diagnosis of autoimmune disorders, viral illnesses such as Hepatitis B/C, HIV, as well as serological tests such as Widal, Rose Bengal, CRP, Rheumatoid Factor[10].

3- **Hematology**: Tests the blood cells and coagulation process. Common tests include a Complete Blood Count (CBC) test, peripheral blood smears, an erythrocyte sedimentation rate (ESR) test and coagulation profile (PT, PTT and INR) to evaluate for anemia, hematological malignancies, and bleeding disorders [11].

4- **Advanced and specialized diagnostics**: Molecular diagnostics such as Real-Time Polymerase Chain Reaction [RT-PCR] assay and automated chemiluminescence immunoassays (CLIA), hormonal profiling (thyroid, reproductive hormone, adrenal assays), tumour markers, metabolic panel and genetic assays that require highly sensitive, specialist instrumentation [12].

FACTORS AFFECT THE ACCURACY AND INTERPRETATION OF RESULTS

Accuracy is being near the true/reference value measured, while precision shows the ability of a test to be repeated or reproduced with the same test conditions. Precise does not necessarily imply accurate[13].

The interpretation and interpretation of clinical test results involves the use of reference intervals, and some technical and biological parameters must be taken into account when making these comparisons:

1. **Analytical sensitivity and specificity**: The smallest amount of the substance that can be found by an analytical and the property of an analytical to identify the substance being sought after and not cross-reacting substances [14].

2. **Method-Specific Reference Intervals**: Normative ranges will vary depending on the analytical platform, reagent manufacturer, demographic population, age and sex.

3. **Biological Variation**: Variations within the individual due to: Circadian Rhythm (e.g., cortisol), biological cycles, physical activity, and nutrition [15].

4. **Instrument Calibration**: To avoid analytical drift, regular calibration of instruments is required, based on certified reference materials, along with calibration traceability.

Possible differences in probability of results and interferences[16].

PROBABILITY OF RESULT DISCREPANCIES AND INTERFERENCES

Inter-laboratory discrepancy is when two or more laboratories report different quantitative and/or qualitative findings on the same person within a relatively short time interval [17].

The risks for discrepancy are in three areas of the diagnostic loop as illustrates in Table (1):

Table1: The diagnostic testing cycle.

Pre-Analytical Phase (~60-70% of Errors)	Analytical Phase (~10-15% of Errors)	Post-Analytical Phase (~15-20% of Errors)
patient preparation	instrument calibration	data transcription
collection/sampling tubes	reagent quality & storage	report generation
hemolysis/clotting	cross-reactivity	misused ingredients[19]
transport and temperature [18]	technical proficiency	

1- Pre-Analytical Interferences

- **Patient non-compliance**: If the patient has not been fasting (or if they have, they may have not been adhering to it), had strenuous exercise, or taken any medication without recording it (such as antibiotics changing microbiology cultures, and biotin interfering with immunoassays).
- **Specimen collection errors**: include the following: Wrong tube choice (e.g. wrong anticoagulant), draw order is incorrect, tourniquet is applied too long resulting in hemo-concentration, mixing is inadequate and causing micro-clots.
- **Sample integrity issues**: In vitro hemolysis, lipemia or icterus affecting spectrophotometric readings.
- **Transport and storage failures**: Transportation delays in sample processing, exposure to ambient heat during transportation from one site to another, or inadequacy in maintaining cold-chain [20, 21].

2- Analytical Interferences

- **Reagent degradation**: Expired, improperly stored, or batch to batch lot variations of reagents.
- **Instrument matrix effects**: Incorrect volumetric pipetting or optical dirty paths, un-calibrated spectrophotometers.
- **Biological interferences**: False elevation or depression of results on immunoassay platforms due to heterophile antibodies, autoantibodies or interfering drugs [22].

3- Post-Analytical Interferences

- **Manual data entry errors:** Errors that occur during data entry in non-integrated or paper logs.
- **Units of measurement inconsistent:** Results are reported in different units (e.g. mg/dl vs. mmol/dl, ng/dl vs. pmol/dl); no information is provided to show how to convert between these units.
- **Inappropriate reference ranges:** Using the same reference values for adults on children or elderly individuals, or using reagent-A values on reagent-B outputs [23,24].

IMPACT OF DISCREPANCIES IN LABORATORY TEST RESULTS ON PATIENTS

Patient trust in the health care delivery system is jeopardized and negatively affects health care quality and treatment if there are discrepancies and inconsistencies between laboratory test results. The medical laboratory is the basis for diagnosis and any abnormality or lack of clarity in the results' accuracy results in the following:

1- Medical uncertainty and confusion: If there is any uncertainty or discrepancy in the results between a patient's first laboratory test and the subsequent result, they start to doubt the results as well, which leads to a loss of trust in the attending physician and the healthcare institution generally [25].

2- Psychological stress and persistent anxiety: Uncertainties in the results especially in relation to critical tests that guide the management of chronic or serious illness, creates tremendous psychological stress for the patient and the fear of receiving the wrong treatment [26].

If the results of the tests do not confirm the diagnosis and the patient becomes skeptical of the correct diagnosis, they may be tempted to ignore medical advice or not take prescribed medications, thinking that they were prescribed incorrectly.

4- Financial burdens, wasted time: Patients feel obliged to have to have a "second opinion" or retest at several laboratories to confirm the results, thus spending unnecessary finances and time before proper medical treatment can begin [27].

5- Alternative scientific; some patients may turn down to the formal medical system due to mistrust, and rely on non-specialists or on medicine that is not founded on science.

6- Institutional mistrust is amplified: When a negative experience with laboratory errors happens, it quickly filters through the public, undermining the credibility of the individual lab or the hospital, and thus reducing community use of the lab/hospital. In areas of weak health systems, lab differences provide confirmation and intensification of public narratives of government underfunding, under-regulation, and/or institutional neglect. An error is never seen in isolation, but quickly becomes 'anecdotal' proof circulating among communities that the entire health-care system is fallible [28].

THE PROPOSED MITIGATION STRATEGIES ARE BASED ON THE RISK FACTORS

Areas requiring improvement, along with the reason for the discrepancy and the proposed solution or preventive action, are summarized in Table (2):

Table 2: Proposed solutions to avoid discrepancies in laboratory results

Factor	Cause of discrepancy	Preventative action or proposed solution
Patient Preparation	Conditions that involve non-standardization of the patient (fasting, medication taking)	Standardized patient instructions sheets (in Arabic, Kurdish and Turkmen) are provided before the sampling; pre-sampling questionnaire is compulsory.
Failure with samples	Hemolysis, wrong tube type, improper draws volume.	Implementing standard phlebotomy procedures; using vacuum collection systems (Vacutainer); using bar-coding for patient and specimen identification.
Transport and Logistics	Thermal degradation in transit between clinics/labs.	Forced cold chain logging procedures with smart temperature data loggers; maximum transit time (< 2 hours for unseparated plasma/serum).
Analytical Equipment	Calibration drift, reagent instability	2 or 3 levels of mandatory daily Internal Quality Control (IQC), scheduled Preventive Maintenance (PM) contracts with certified vendors.
Assay Variability	Inter laboratory method bias	Compliance with international reference standards (NIST/WHO standards); External Quality Assessment (EQA) schemes.
Data and Reporting	Manual entry errors, unit errors	Automated Laboratory Information Management Systems (LIMS) with direct interfacing with the analyzer and Automated flag alerts for Panic values.

LABORATORY PERSONNEL TO AVOID DISCREPANCIES

Laboratory scientists, technicians and pathologists are on frontline in preventing diagnostic errors. Their responsibilities include:

- 1- Flexibility with verification of standard operating procedures (SOPs): Strict adherence to verified laboratory SOPs through the pre-analytical, analytical and post-analytical phases of testing.
- 2- As quality control verification: where IQC has flagged an event for possible rules violations, obstinately refusing to release clinical runs.
- 3- Continuous professional development: Ongoing training/mentoring in phlebotomy technique, automated instrumentation, trouble-shooting analytical flags and safety standards.
- 4- Sample quality rejection criteria: Hemolysis, clotted, QNS or wrongly labeled specimens are strictly rejected against the external pressure.
- 5- Impactful communicating with treating physicians: Active communication with treating physicians prior to releasing abnormal or clinically significant results to confirm unexpected test results and seeking clinical correlation when there is discordance between clinical presentation and laboratory results[29].

Directorate of health and regulatory oversight in Kirkuk

Systemically addressing this discrepancy and restoring public confidence in neighbourhood health services will demand one regulatory and structural Governance Framework that should be executed locally by the Kirkuk Directorate of Health, with a coordination role from the Iraqi Ministry of Health:

Directorate of health governance model

- 1- Compulsory licensing and accreditation (ISO 15189 Standards)
- 2- National external quality assessment programs
- 3- Unannounced technical audits and inspection teams
- 4- Standardized regional reference intervals
- 5- Transparency in public, patient advocacy and complaints.

1- Mandatory accreditation and licensing standards

- Implementation of accreditation frameworks based on international standards, such as ISO 15189 for all the public and private clinical laboratories in Kirkuk Governorate.
- Re-licensure should be required periodically if technical competency evaluations and facility inspections are passed [30].

2- Development of a provincial external quality assessment (EQA) program

- Create an organize reference laboratory under the management of Kirkuk city directorate of health to distribute blind proficiency testing samples every month to all registered private sector facilities.
- Monitor inter-laboratory comparability and publicly index performance outcomes [31].

3- Unannounced audits and quality inspections

- Verify sensitive information files and ensure they include cold storage (temperature records), reagent supply chains, equipment calibration logs, and technician qualifications, disposal procedures through technical inspection teams for private and public labs.
- Penalize non-compliant facilities by issuing fines, temporary suspensions, or revoking licenses [32].

4- Quality control and importation of reagents standardization

- Monitor and enforce the quality of diagnostic kits and reagents being imported to the Kirkuk Governorate, along with where products will be stored so that sub-standard or poorly-conditioned supply lines can be shut down [33].

5- Public trust and awareness initiatives

- Engage in public communication campaigns to raise awareness of reasons for minor inter-laboratory variations and appropriate report interpretation.
- Fortify directorate of health with a formalized complaint and review process where patients can escalate severe laboratory discrepancies for objective clinical evaluation [34].

CONCLUSION

The high prevalence of conflicting laboratory results is a serious issue concerning the diagnostic reliability, which is mainly due to pre analytical problems including the inappropriate collection of samples, patient preparation, and the transport logistic problems. It is the responsibility of the laboratory staff to maintain a standard operating procedure and ongoing professional development to help eliminate technical and analytical drift. At the same time, the Directorate of Health needs to put in place strict control by complying with international accreditation requirements, implementing a centralized proficiency testing program, and auditing

Discrepancies in Laboratory Test Results and Their Impact on Patient Confidence in The Health System in Kirkuk, Iraq

compliance with the facilities. It can help to prevent these avoidable diagnostic mistakes, reduce the unnecessary financial and physical burden on patients, and return public trust in the medical system, by promoting a culture of transparency, technical accountability, strict quality control, and accountability.

REFERENCES

- 1) Shedura VJ, Malindisa KK, Nanyanga SJ. Implementation of laboratory quality management system: A cornerstone for enhanced patient safety and clinical outcomes in Tanzania. *Emerging infectious diseases*. 2025 Oct 16;3:4.
- 2) Ghareeb OA, Ali QA. Assessment of Proinflammatory Cytokine Responses in Arsenic-Induced Hepatotoxicity: An in vivo Study. *Biological Science: Research Developments and Innovations Vol. 1*. 2026:1-5.
- 3) Olver P, Bohn MK, Adeli K. Central role of laboratory medicine in public health and patient care. *Clinical Chemistry and Laboratory Medicine (CCLM)*. 2023 Mar 28;61(4):666-73.
- 4) Plebani M, Cadamuro J, Vermeersch P, Jovičić S, Ozben T, Trenti T, McMillan B, Lowe CR, Lennerz J, Macintyre E, Gabelli C. A vision to the future: value-based laboratory medicine. *Clinical Chemistry and Laboratory Medicine (CCLM)*. 2024;62(12):2373-87.
- 5) Chu F, Shi M, Liu C, Zhu J. Discrepancy in clinical and laboratory profiles of NMOSD patients between AQP4 antibody positive and negative: can NMOSD be diagnosed without AQP4 antibody?. *Clinical and Experimental Immunology*. 2023 1;213(3):363-70.
- 6) Mirham L, Hanna J, Yousef GM. Addressing the diagnostic miscommunication in pathology: old challenges and innovative solutions. *American Journal of Clinical Pathology*. 2021 Oct 1;156(4):521-8.
- 7) Qianqian G, Pratama IH. Public Trust in Laboratory Results During Emerging Infectious Disease Alerts. *Link Medical Journal*. 2026 Jun 24;4(1):1-1.
- 8) Najat D. Prevalence of pre-analytical errors in clinical chemistry diagnostic labs in Sulaimani city of Iraqi Kurdistan. *PloS one*. 2017 Jan 20;12(1):e0170211.
- 9) Ogoto AC, Agwaranze DI, Daji M, Aso RE. Microbial techniques and methods: Basic techniques and microscopy. In *Analytical techniques in biosciences*. 2022: 201-220.
- 10) Turgeon ML. *Immunology & Serology in Laboratory Medicine-E-Book: Immunology & Serology in Laboratory Medicine-E-Book*. Elsevier Health Sciences; 2020 Dec 16.
- 11) Keohane EM, Preston MM, Mirza KM, Walenga JM, editors. *Rodak's hematology-e-book: clinical principles and applications*. Elsevier Health Sciences; 2024 Apr 15.
- 12) Buckingham L. *Molecular diagnostics: fundamentals, methods and clinical applications*. FA Davis; 2019 Feb 22.
- 13) Mehl A, Reich S, Beuer F, Güth JF. Accuracy, trueness, and precision-a guideline for the evaluation of these basic values in digital dentistry. *International Journal of Computerized Dentistry*. 2021 Oct 1;24(4):341.
- 14) Barra GB, Santa Rita TH, Mesquita PG, Jácomo RH, Nery LF. Analytical sensitivity and specificity of two RT-qPCR protocols for SARS-CoV-2 detection performed in an automated workflow. *Genes*. 2020 Oct 12;11(10):1183.
- 15) Franzago M, Alessandrelli E, Notarangelo S, Stuppia L, Vitacolonna E. Chrono-nutrition: circadian rhythm and personalized nutrition. *International journal of molecular sciences*. 2023 Jan 29;24(3):2571.
- 16) Shukla SS, Pandey RK, Gidwani B, Kalyani G. Calibration methods and procedures. In *Pharmaceutical Calibration, Validation and Qualification: A Comprehensive Approach 2023 Feb* : 29-40. Singapore: Springer Nature Singapore.
- 17) Jirkof P, Abdelrahman A, Bleich A, Durst M, Keubler L, Potschka H, Struve B, Talbot SR, Vollmar B, Zechner D, Häger C. A safe bet? Inter-laboratory variability in behaviour-based severity assessment. *Laboratory animals*. 2020 Feb;54(1):73-82.
- 18) John GK, Favaloro EJ, Austin S, Islam MZ, Santhakumar AB. From errors to excellence: the pre-analytical journey to improved quality in diagnostics. A scoping review. *Clinical Chemistry and Laboratory Medicine (CCLM)*. 2025 Jun 26;63(7):1243-59.
- 19) Moore R. *Preanalytical Errors, Analytical Errors, and Postanalytical Errors and Financial Performance of Hospitals (Doctoral dissertation, Walden University)*. 2025.
- 20) Plebani M. Quality indicators to detect pre-analytical errors in laboratory testing. *The Clinical Biochemist Reviews*. 2012 Aug;33(3):85.
- 21) Lima-Oliveira G, Volanski W, Lippi G, Picheth G, Guidi GC. Pre-analytical phase management: a review of the procedures from patient preparation to laboratory analysis. *Scandinavian journal of clinical and laboratory investigation*. 2017 Apr 3;77(3):153-63.
- 22) Abdollahi A, Saffar H, Saffar H. Types and frequency of errors during different phases of testing at a clinical medical laboratory of a teaching hospital in Tehran, Iran. *North American journal of medical sciences*. 2014 May;6(5):224.
- 23) Plebani M, Thelen M, Zaninotto M, Dukic L, Cavalier E, Huggett J, De La Salle B, Busby EJ, Favaloro EJ, Dimech W,

- Smeets RL. Harmonization of measurement units: mission impossible or ethical imperative?. *Clinical Chemistry and Laboratory Medicine (CCLM)*. 2026 Jul 1(0).
- 24) Zaninotto M, Plebani M. Understanding and managing interferences in clinical laboratory assays: the role of laboratory professionals. *Clinical Chemistry and Laboratory Medicine (CCLM)*. 2020 Feb 25;58(3):350-6.
- 25) Evans I, Thornton H, Chalmers I. *Testing Treatments: Better Research for Better Healthcare*. London: Pinter and Martin, 2010.
- 26) van Moll C, Egberts T, Wagner C, Zwaan L, Ten Berg M. The nature, causes, and clinical impact of errors in the clinical laboratory testing process leading to diagnostic error: a voluntary incident report analysis. *Journal of patient safety*. 2023 Sep 28;19(8):573.
- 27) Horvath AR. From evidence to best practice in laboratory medicine. *The Clinical Biochemist Reviews*. 2013 Aug;34(2):47.
- 28) Webb Hooper M, Mitchell C, Marshall VJ, Cheatham C, Austin K, Sanders K, Krishnamurthi S, Grafton LL. Understanding multilevel factors related to urban community trust in healthcare and research. *International journal of environmental research and public health*. 2019 Sep;16(18):3280.
- 29) Cornish NE, Anderson NL, Arambula DG, Arduino MJ, Bryan A, Burton NC, Chen B, Dickson BA, Giri JG, Griffith NK, Pentella MA. Clinical laboratory biosafety gaps: lessons learned from past outbreaks reveal a path to a safer future. *Clinical microbiology reviews*. 2021 Jun 16;34(3):10-128.
- 30) Huber M, Andreyeva M, Presser LD, Zwetyenga JS. Health laboratory licensing: a policy and best-practice analysis. *Bulletin of the World Health Organization*. 2025 3;103(6):383.
- 31) Chen D, Mo H, Zhang Y, Qin J, Zhang L, Jiang C, Li F, Zhang X, Ou T. Development and implementation of an internal quality control and external quality assessment information system for a regional medical laboratory center: Pilot design and implementation study. *JMIR Formative Research*. 2025 Dec 9;9:e77043.
- 32) Roy S, Mandal B, Das BK. Quality assurance in laboratory practices and equipment maintenance: Ensuring precision, reliability, and compliance. In *Laboratory Techniques for Fish Disease Diagnosis* 2025 May 1 : 79-103.
- 33) Carey RB, Bhattacharyya S, Kehl SC, Matukas LM, Pentella MA, Salfinger M, Schuetz AN. Practical guidance for clinical microbiology laboratories: implementing a quality management system in the medical microbiology laboratory. *Clinical microbiology reviews*. 2018 Jul;31(3):10-128.
- 34) Bonar R, Favalaro EJ. Explaining and reducing the variation in inter-laboratory reported values for International Normalised Ratio. *Thrombosis Research*. 2017 Feb 1;150:22-9.