

Research Article

# National Survey on Delta check Practices in Clinical Laboratories Across Pakistan

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## Article Info

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## Abstract

**Background:** Delta check is a quality control tool in clinical laboratory that compares a patient's current test results with previous ones. It is often considered to be a useful tool to identify pre-analytical errors. Delta check procedures vary across labs. A survey was conducted to determine national delta check practices.

**Method:** An online survey was sent to pathologists. Data was analyzed by Microsoft excel and figures were generated via R statistical software.

**Results:** The survey was sent out to 84 participants. There were 30 (35.7%) final responses, after exclusion of duplicates and incomplete entries. Respondents varied in their designations from Professor 2(6.7%) to Assistant Professor 10(33.3%). Most respondents 25 (83.3%) were Fellows of College of Physicians and Surgeons, while there were 3(10%) PhDs. Work experience varied from less than 3 years, 5(16.7%) to more than 10 years, 17(56.7%). 25 labs surveyed were from tertiary care hospitals. Most laboratories were in Sindh Province, 13 (43.3%). Delta check procedures were used by 19(63.3%) labs, of which 6(31.6%) used automated checks, 12(63.2%) had defined delta limits for different tests, 15(78.9%) had defined time limits to check delta results, 17(89.5%) had a checklist for its investigation and 10(52.6%) had a Laboratory Information System or middle-ware to block failed delta results. Most of the respondents considered the smallest available option as the ideal delta difference value for blocking results.

**Conclusion:** Delta check procedures vary among surveyed labs and efforts are required for the formulation of national guidelines to synchronise and standardize delta check practices.

## Introduction

Delta check is a mode of patient-based real time QC (PBRTQC) used in clinical laboratories in which difference between sequential patient results help to identify potential pre analytical, analytical or post analytical errors. The earliest work on delta check procedures in clinical laboratory is from 1970s [1, 2]. Its greatest utility is suggested to be in picking up pre-analytical errors [3-5], although the use of wrist bands for patients' identification and scanners for its confirmation, bedside bar code labelling, electronic ordering and receiving of specimens, and automated hemolysis, icterus, lipemia (HIL) checks have reduced these errors [6]. With the advent of automation, interfacing of instruments with Laboratory Information System (LIS) and use of middle wares, post analytical errors such as transcriptional or calculation mistakes have also decreased. Analytical faults account for the least percentage of these errors. The most common cause of significant difference between two serial results is due to change in physiological condition [5, 7].

Delta checks are also an inherent part of most auto-verification algorithms and have been recommended in various latest guidelines[8-10]. Clinical and Laboratory Standards Institute (CLSI) guideline EP33 ED2:2023 explains in depth the calculations and utilities of delta checks [11], while College of American Pathologists (CAP) has incorporated clauses related to delta checks in the accreditation checklist's section on auto-verification.

National surveys are a good tool for gaining an insight into the current practices and identifying the need to improve upon them. Data collection is relatively simple. A drawback is the reliance on the participants for the availability and validity of the responses. The aim of conducting this survey was to acquire baseline knowledge regarding current delta check procedures across different laboratories in the country and to identify the existing gaps. The results of the survey will be used for capacity building of the clinical laboratory fraternity, and aim to make recommendations for formulation of national guidelines for standardizing the use of delta checks in reporting patient test results.

## Material and Methods

The survey was conducted from December 2024 to January 2025 after IRB approval # IHHN\_IRB\_2024\_11\_004 and in accordance with Declaration of Helsinki (2024). The

questionnaire was prepared on RedCap which is a web-based questionnaire tool, and sent out to a total of 84 pathologists working in clinical laboratories across Pakistan selected by snowball technique. Pathologists with whom contact already existed were asked to give contacts of other potential participants. Consent of the participants was taken in the questionnaire.

Inclusion criteria included Chemical Pathologists, Haematologists, Heads of department or consultants working in clinical laboratories across Pakistan and holding Fellowship of College of Physicians and Surgeons, Pakistan (FCPS), Masters of Philosophy (MPhil) or Doctor of Philosophy (PhD) degrees. Exclusion criteria included duplicate entries from same lab and incomplete responses. The questionnaire was sent via WhatsApp or email to the various participants. In the first section of the survey, general details of the participants and the hospital/ laboratory was gathered. The second part dealt with their laboratory practices related to delta check procedures. The participants were then asked about what delta check limits they thought should be used for various laboratory tests, including calcium, sodium, potassium, chloride, bicarbonate (HCO<sub>3</sub>), urea, creatinine, uric acid, cardiac troponins, HbA<sub>1c</sub>, haemoglobin, white blood cell (WBC) count, platelet count and International Normalized ratio (INR).

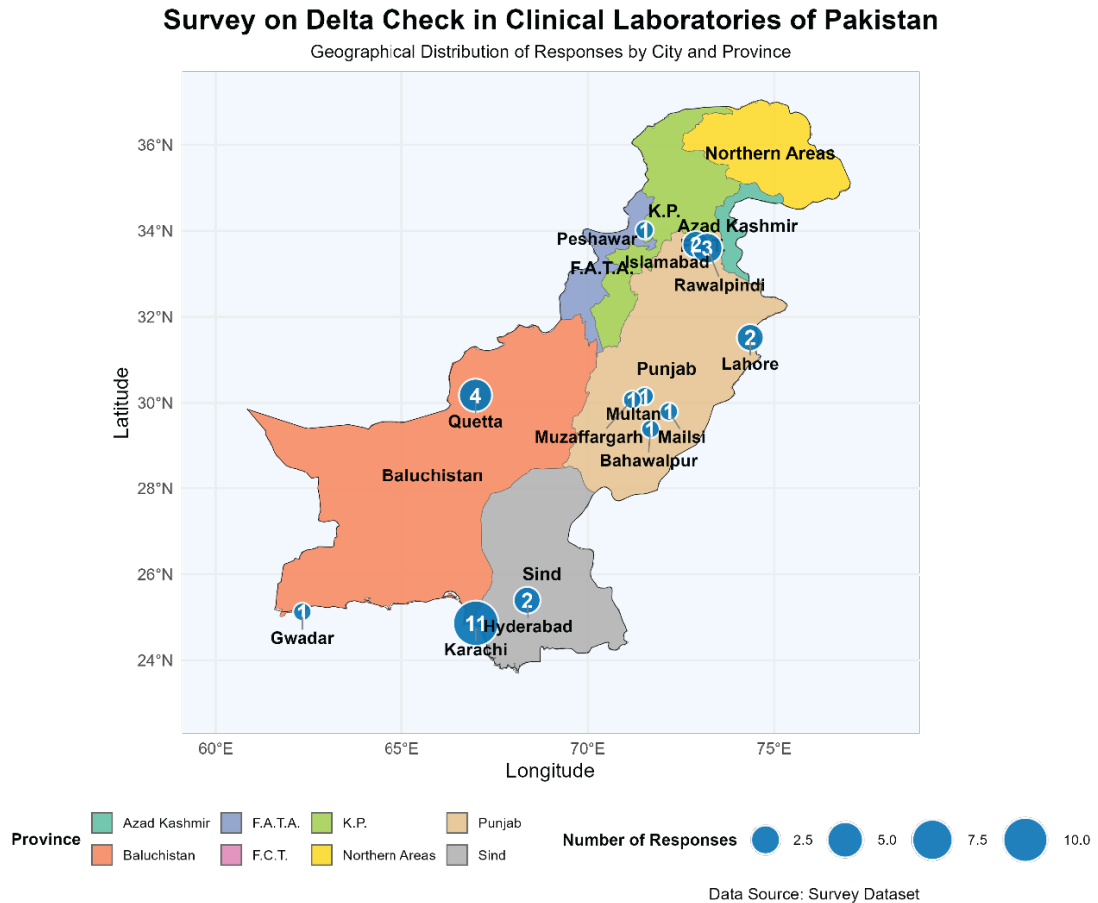
Results were analyzed by Microsoft Excel version 2511.

Frequencies and percentages were calculated for the various variables. R statistical software was used to create figures.

## Results

The survey was sent out to 84 participants. There were 30 (35.7%) final responses, after exclusion of 4 duplicates and one incomplete entry. Respondents varied in their designations from Professor 2 (6.7%) to Assistant Professor, 10 (33.3%). Majority of the respondents 25 (83.3%) were FCPS, while there were 3 (10%) PhDs. Work experience varied from less than three years, 5 (16.7%) to more than 10 years, 17 (56.7%), while there were 4 (13.3%) pathologists each with 3-5 and 5-10 years of experience. The survey participants included pathologists from Federal Capital Territory and all four provinces of Pakistan, (Sindh, Baluchistan, Punjab and Khaybar Pakhtunkhwa). Sindh had the largest representation, 13 (43.3%) of which the city of Karachi had the most labs, 11 (36.6%). Next highest representation was from Punjab 9 (30%), (Figure 1).

**Figure 1:** Map of Pakistan showing number of labs and their cities included in the survey.



The respondents belonged to various laboratory types, predominantly from labs based in tertiary care hospitals, 25 (83.3%), while 4 (13.3%) were from labs in secondary care hospitals and 1 (3.3%) from a stand-alone laboratory. Hospitals

of various bed strengths were covered and majority of them were moderately sized having 100-500 beds, 19 (65.5%). Survey questions and the responses regarding the clinical laboratories' practices are mentioned in Table 2.

**Table 2:** Responses to questions related to laboratory practices.

Variable	Options	Frequency (Percentage)
Laboratory type (n=30)	Laboratory in a secondary care hospital	4 (13.3)
	Laboratory in a tertiary care hospital	25 (83.3)
	Stand-alone laboratory	1 (3.3)
Hospital beds (n=29)	0-50	1 (3.4)
	50-100	1 (3.4)
	100-500	19 (65.5)
	> 500	8 (27.6)
Clinical laboratory accreditation	No	12 (40)
	Yes	18 (60)
If yes: (n=18)	CAP-accredited	3 (16.7)
	ISO 15189 accredited	8 (44.4)
	Other	7 (38.9)
Presence of laboratory information system in clinical laboratory (n=30)	No	6 (20)
	Yes	24 (80)

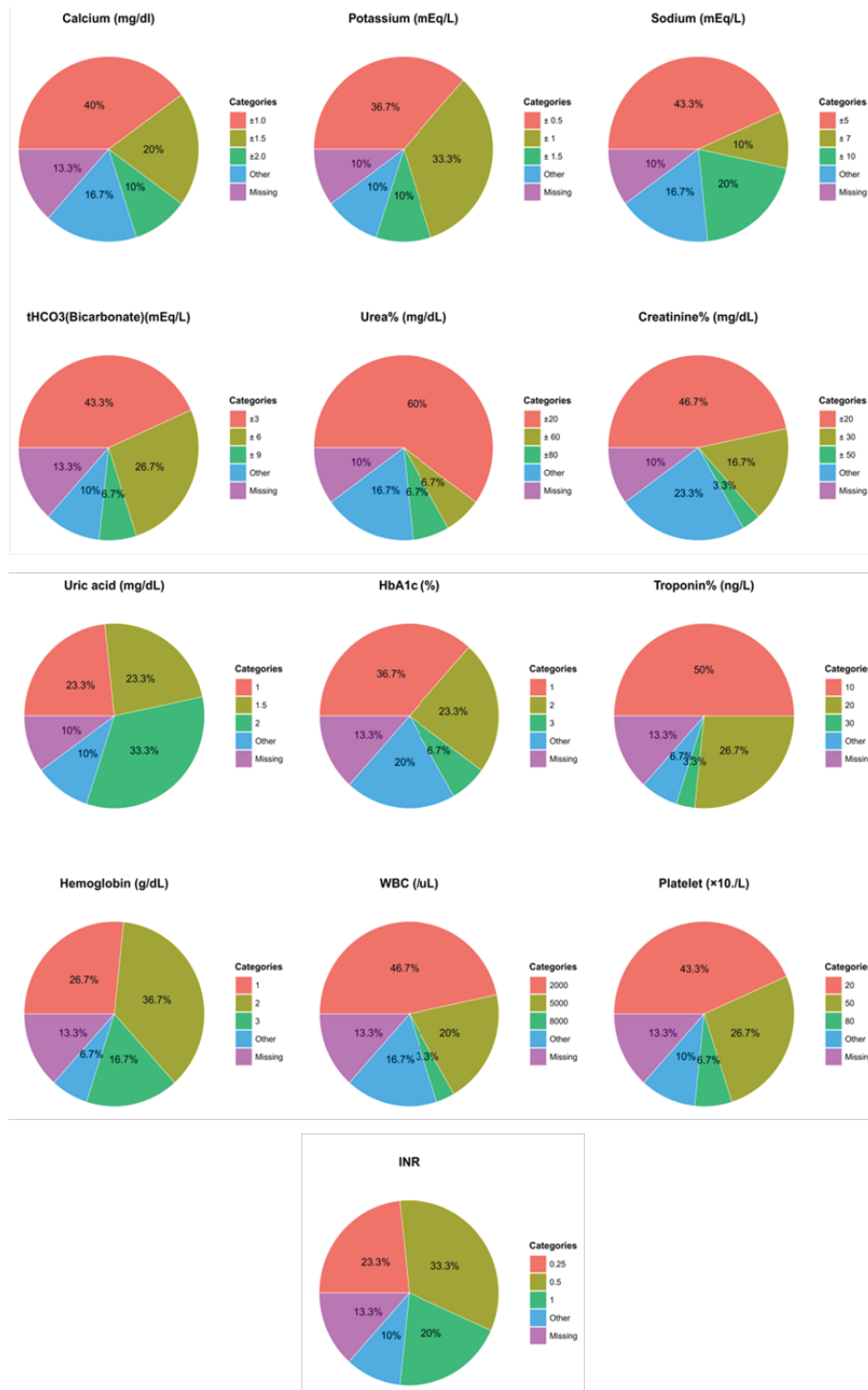
Variable	Options	Frequency (Percentage)
Mode of test reports in clinical laboratory? (n=30)	Electronic reports	6 (20)
	Printed paper reports	4 (13.3)
	Both electronic and printed reports	20 (66.7)
Interfacing of results to laboratory information system and reports (n=30)	No	10 (33.3)
	Yes	20 (66.7)
Auto-verification procedures (n=30)	No	22 (73.3)
	Yes	8 (26.7)
Delta check procedure before releasing the patients results (n=30)	No	11 (36.7)
	Yes	19 (63.3)
Delta check procedure manual or automated (n=19)	Automated	6 (31.6)
	Manual	13 (68.4)
Time period defined for checking delta results (n=19)	No	4 (21.0)
	Yes	15 (78.9)
If yes, what is the defined time period? (n=15)	1 day	1 (6.7)
	1 week	1 (6.7)
	3 days	2 (13.3)
	Dependent on the type of the test	11 (73.3)
Are parameters defined for which a delta check is required? (n=19)	No	9 (47.4)
	Yes	10 (52.6)
Are Delta check limits defined for each type of test or dependent on the laboratory staff? (n=19)	No, dependent on the laboratory staff	7 (36.8)
	Yes, defined delta check limit	12 (63.2)
How are delta limits defined? (n=12)	From the literature survey	6 (50)
	From the labs own data	4 (33.3)
	By Reference Change Value (RCV) based on intra/inter-individual variation	2 (16.7)
Checklist to work out the possible causes of delta failure (n=19)	No	2 (10.5)
	Yes	17 (89.5)

CAP: College of American Pathologists, ISO: International Organization for Standardization, LIS: Laboratory Information System

There were 18 clinical laboratories which were accredited out of which 3 (16.7%) labs were accredited by CAP, while 8 (44.4%) were International Organization for Standardization (ISO) 15189 accredited. Other labs mentioned accreditation by ISO 9000, ISO 9001, Punjab Healthcare Commission and Joint Commission International (JCIA). Most of the labs surveyed, 24 (80%) had an LIS and 20 (66.7%) percent said that their laboratory results were interfaced to LIS. A total of 8 labs (26.7%) claimed to have an auto-verification system, while 19 (63.3%) said they have placed a procedure for delta checks before releasing patient results. The specific variations in delta check practices are mentioned in Table 2.

The opinion of the participants for delta check limits of various common analytes is shown in Figure 2. When a participant did not give any opinion for these delta check limits, it is labelled as missing. In the opinion of 11 (37%) participants appropriate delta for potassium was  $\pm 0.5$  mEq/L while delta limit for sodium was suggested as  $\pm 5$  mEq/L by 13 (43%) respondents. For both urea, 18 (60%) and creatinine, 14 (47%) participants considered  $\pm 20\%$  change as the most suitable delta limit.

**Figure 2:** Participants' opinion on optimal delta limits for common analytes.



**Discussion**

This is the first survey conducted in Pakistan on delta checks practices in clinical laboratories. Amongst the labs surveyed, 19 (63.3%) used delta check procedures in their labs. A lab survey conducted on clinical laboratories in Spain revealed a response rate of 13.2%, [12], while in China a similar survey showed the response rate as 24.7% [7]. Our response rate in comparison is 30(35.7%). The overall number of labs in our survey is not very high, yet this is the usual response rate received in various clinical laboratory surveys conducted in Pakistan [13, 14]. The

higher participation of senior pathologists from medium to large sized labs could be due to their greater understanding and sensitization for the topic. The snowballing technique used in reaching out to the participants had its disadvantages as the immediate contacts responded more frequently than those who were approached through secondary contacts. Hesitation to share information regarding institutional practices, not being familiar or acquainted with the survey topics and lack of time or interest could be the other reasons for not participating in the survey. Since systematic implementation of delta check procedure

requires an advanced LIS or middleware which is not available in most of the clinical laboratories in Pakistan, it is possible that the pathologists without access to these resources refrained from participating in the survey.

A Croatian survey on medical laboratories showed that 30% used delta checks in their labs [15]. In the Spanish survey delta checks were being used in 24% of the labs [12] and in China, delta check was used by 25% of the labs surveyed [7]. Usage of delta check procedures in our survey, 19 (63.3%), is probably greater compared to other surveys because of more participation by tertiary care institutes in this survey.

The analytes considered good candidates for delta are those with low index of individuality or low intra individual variation [4, 16, 17]. Reference change value (RCV), which is based on intra individual biological variation, is accepted by CLSI as a tool to set the limits [11]. In our survey only 2 labs mentioned that they used RCV to set their delta limits, while 6 used literature-based values. However, RCV limits need to be verified and optimized to prevent high number of false alarms [18].

Auto-verification was stated to be present in 8 (26.7%) of the labs surveyed, although the extent of auto-verification was not asked. A global survey published in 2024 covering 920 labs from 55 countries, showed auto-verification was used in 10% labs [9]. Another study showed less than 20% of hospital labs were engaged in auto verification [19]. Overall, as other surveys have reported across Europe and Middle East, currently information technology in clinical laboratory is underutilized, even for the basic functions [9, 19, 20]. An alarming revelation during our survey, which is a testimony to this fact, is that one third of the labs surveyed did not have result interfacing. Implementing a delta check rule, albeit manual, would be of paramount importance in these cases to catch transcription errors.

Out of the 19 labs which had a delta check procedure in place in our survey, majority, 17, had a checklist for working on the delta check failures. Investigation check list or algorithms for trouble shooting delta failures are important to delineate the root cause, and these should focus on all three testing phases.

Ideal time gap between the two results to elicit delta failure can vary depending on the parameter, patient setting (inpatient versus outpatient), and other factors. This varies greatly with the laboratory practice worldwide [4]. Clinical specimens are not generally stored for more than one week and there are stability issues for many parameters. Previous specimen is also ideally required for delta investigation. These factors together call for practical constraints in setting delta time limits. Keeping a long time period may give more false alerts as certain analytes may change over time for variable reasons, for example; disease state, patient management, transfusion and dialysis. An exception is HbA1c in which the optimal time is three months because of red blood cell turnover time. Keeping variable time frames for different tests might be hindered by the available LIS or middleware in the lab. CAP Q probe study showed that median time span was 3-7 days for the routine assays [5] while Tan et al state that there is no ideal time limit cut off [21]. HbA1c was not included in these studies.

Most of the respondents chose the smallest option as the optimal delta difference for the analytes surveyed. Notable exception was

for haemoglobin where majority selected a difference of 2.0 gram/decilitre as a significant change, which was also the median delta limit pointed out in CAP Q probes [5]. For sodium, majority, 13 labs preferred the delta limit as 5.0 mEq/L, while in CAP Q probes study the median sodium delta change limit was 9.0 mEq/L [5]. Similarly for Calcium the delta limit chosen by 12 labs was 1.0 mg/dL, while in the CAP Q probe study a median of 2.0 mg/dL was identified [5]. Another obvious discrepancy was in total CO<sub>2</sub> or bicarbonate in which 13 (43%) labs in our survey mentioned that 3.0 mEq/L should be kept as the delta limit, while in CAP Q probes the median delta limit was 8.0 mEq/L [5]. The underlying point is that delta checks limits should be optimized such that there are minimum false alarms. Physiological changes account for most delta alerts. A very narrow range can give unnecessary alarms thus increasing the turnaround time and resource wastage. It is important to optimize the delta limits and review them periodically. Similarly, the limits should not be so relaxed as to miss the alarms [4, 17].

Although 19 laboratories reported having a delta check process in place, more responses were received when participants were asked to specify ideal delta limits for various parameters. This suggests that while pathologists had parameter specific delta cut-off values in their minds, these had not been implemented, possibly due to limitations in IT support systems.

The various calculations suggested to determine the delta threshold are absolute delta check, percentage delta check, absolute rate difference delta and percentage rate difference delta. These depend on whether absolute numerical values or percentages are used and with or without time scale. While absolute delta checks are appropriate for parameters such as sodium and chloride where the analytes are kept in strict physiological limits, percentage change is more relevant for urea and creatinine specially at higher values. For an analyte such as neonatal bilirubin, time scale is very significant. Multivariate delta or delta difference across multiple parameters can be more useful to point towards a cause, for example, urea and creatinine, ALT and AST, serum protein and albumin [10]. Gender specific absolute delta thresholds for cardiac troponins have been suggested [22], with researchers suggesting a delta limit of 10 ng/L for men and 7.0 ng/L for women. Urea and creatinine delta limits in patients on dialysis do not hold much value and give false alarms. Other calculations have been proposed for these patients [23]. International Normalized Ratio (INR) is a well-known marker performed widely for screening patients for coagulopathy. Various INR cut-offs have been used for different conditions [24], and the laboratory practices must be aligned with the current clinical practice guidelines. Evidence-based approaches, including retrospective data analysis and receiver operating curve (ROC) evaluation, are increasingly used to set and verify delta check limits tailored to local clinical and operational needs [23, 25, 26]. Multianalyte and logistic regression-based delta checks improve detection of contamination by intravenous fluid and preanalytical errors, reducing false alert rates and enhancing specificity [26, 27]. A clinically pertinent use of delta is a real time alert system based on delta differences for selected clinical conditions, including acute myocardial infarction (AMI) and acute kidney injury

(AKI). In 2012, researchers stated that introducing electronic alerts for AKI could improve short term clinical outcome and intervention [28]. N Flynn and A Dawney did a study on real-time automated delta check electronic alerts flagging a 50% increase in creatinine to a concentration of >50 mmol/L from the last result within 90 days and saw that 70% of the delta alerts were due to AKI [29]. Consensus document from Acute Disease Quality Initiative meeting concluded that digital health solutions provide enhanced tools to improve AKI care with on going improvements in diagnosis and monitoring [30]. This survey does not give a snapshot of all laboratories in Pakistan, though it does provide a very true picture of the specialized labs and their practices related to delta checks. Detailed information about the methodology and criteria for application of delta rule for each parameter was not asked in the survey. The next phase will be to conduct educational sessions for implementation of delta checks focussing on causes, delta work up checklists, algorithms and calculations. Sporadic educational activities in Pakistan on this topic have taken place over the years, however, with increased awareness and growing number of laboratories, this topic needs to be re-addressed in detail. Consistent usage of optimal delta check for identifying total testing process errors is required. It can also be made a key performance indicator (KPI) for continual quality improvement. Individual variations in delta procedures will exist depending on the laboratory set-up and its requirements. We propose a National Working Group under the umbrella of the Pakistan Society of Chemical Pathology (PSCP) for quality improvement initiatives, with one of the aims to elevate the reporting standards and standardize patient test reporting practices.

#### Limitations

The number of laboratories surveyed is small, nevertheless, they span Federal Capital and all four provinces, and include a large number of subject experts and some of the major hospitals of the country. Participation and response biases are other limitations of such survey designs [31].

#### Conclusion

Delta check practices vary across clinical laboratories in Pakistan. There is need to formulate and implement National guidelines for the standardized use of delta check practices in routine clinical laboratory operations.

#### Conflict of Interest

None declared.

#### Ethical Statement

Expedited ethical approval was granted by the Institutional review board (IHHN\_IRB\_2024\_11\_004) in accordance with Declaration of Helsinki.

#### Author contributions

Fatima Kanani: Conceptualization, methodology, software, analysis, initial draft, review and editing  
Saba Raza: Methodology, review  
Harim Fatima: Software, initial draft  
Adnan Mustafa Zubairi: Methodology, resources, review

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#### Data Availability

Study data is available on request from the corresponding author according to institutional policies.

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