What is the best tool currently available for detecting specimen misidentification?

Use of Delta Checks: A Requisite Method in Quality Control

Sedef YENICE

IFCC Committee on Clinical Laboratory Management - http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

Satellite Educational Workshop on Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement

Hilton Durban - October 22, 2017

Presentation Outline

- Definitions and Approaches to establishing delta check limits
- Selecting analytes for which delta checks are useful
- Developing rules for comparing them to previous results
- Investigating specimens with delta check alerts
- Evaluating the effectiveness of the laboratory's delta check systems

What should be the policy if discrepant results occur?

A Sentinel Event:

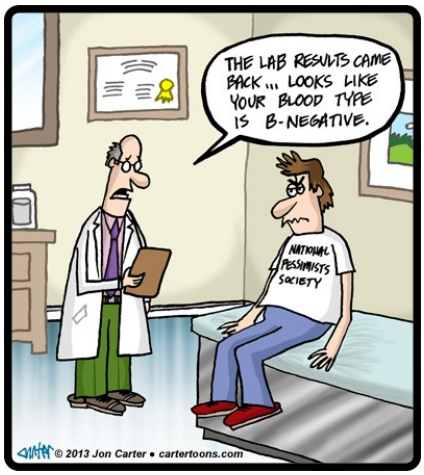
- ❑ **Delta check** alert appeared on several chemistry and hematology results for an individiual patient.
- «**Delta MCV**» called the nurse on ward; nurse acknowledged receipt; hematology results released to the patient chart
- **Delta chemistry** results were confirmed; results released to the patient chart

What should be the policy if discrepant results occur?

- Type and cross was performed for transfusion
  - Patient had no previous ABO history for comparison
- Patient was given 2 units of blood and experienced a transfusion reaction

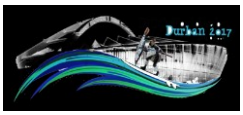
What happened?

What should be the policy if discrepant results occur?



The wrong patient was drawn...

Presentation Outline



- **Definitions and Approaches to establishing delta check limits**
- Selecting analytes for which delta checks are useful
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Delta Check: Definition*

- A comparison of two consecutive results from the same patient, based on specified criteria, as a **quality improvement effort** by the lab.
- The difference between the two sets is compared to a predefined limit that is specific for the measurand/analyte within a predefined length of time.
- Addresses **errors** that are not detectable with other methods of QC; assesses pre-, analytical, post – errors.

*) CLSI. Use of Delta Checks in the Medical Laboratory. 1st ed. CLSI Guideline EP33. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Two Main Goals:

Changes in patient condition

Sample quality issues and patient misidentification

The Concept of Delta Checks

1967

The use of delta check rules in lab medicine as a patient-based quality control method was introduced by Lindberg in 1967 as a new concept related to emerging technology in laboratory informatics.

1974

Nosanchuk and Gottman introduced as a **QC technique to identify misidentified specimens**. They used manual checking.

Am J Clin Pathol. 1974;62(5):707-712.

1975

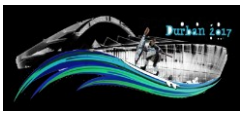
Ladenson described the **first use of computers to compare patients current and previous specimens in real time** as results are reviewed.

Clin Chem. 1975;21(11):1648-1653.

Present

This basic approach to identifying significant delta checks **changed little** in the ensuing 42 years.

Presentation Outline



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Audience Response

Does your laboratory has written criteria describing specific actions required to handle delta check alerts?

1. **Yes**
2. **No**

Audience Response

Is the frequency of delta check events monitored as part of quality assurance or other assessment process?

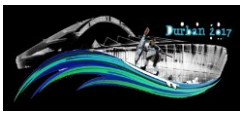
1. **Yes**
2. **No**

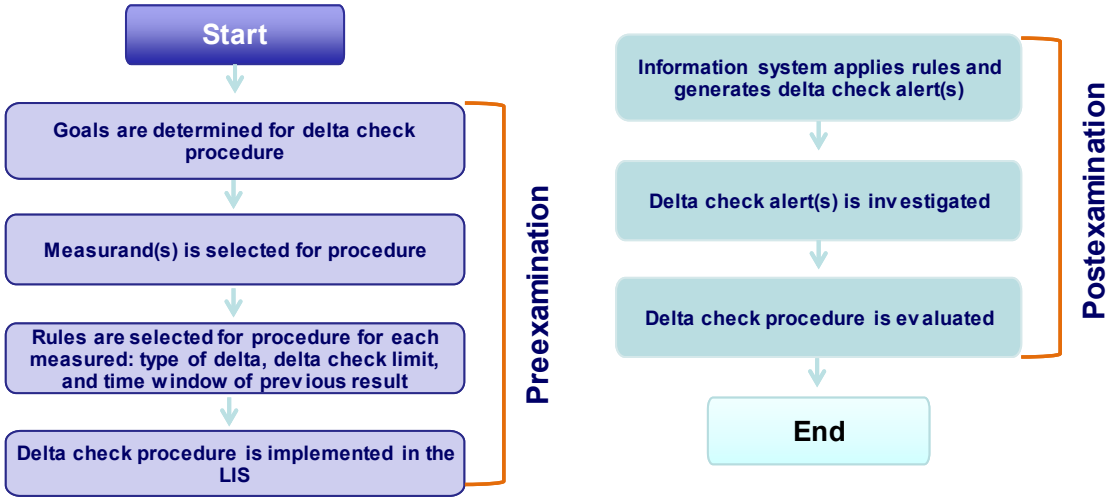
Audience Response

Is a checklist in use to handle delta check alerts?

1. **Yes**
2. **No**

What is the Process Flow Chart for Using Delta Checks?





CLSI. Use of Delta Checks in the Medical Laboratory. 1st ed. CLSI Guideline EP33. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Determining Goals for the delta check program

4 primary goals for delta checks:

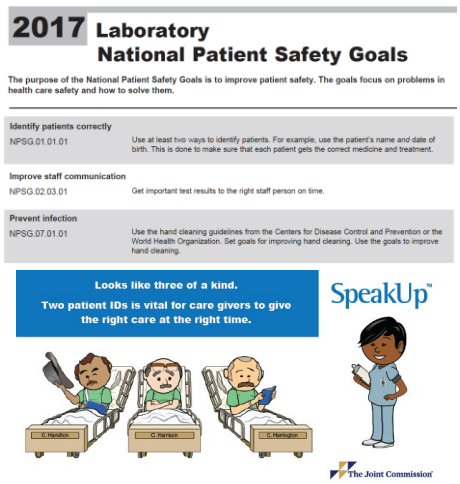
- Screen for **misidentified** specimens
- Detect **specimen integrity** problems such as hemolysis and IV contamination
- Detect examination (**analytical**) issues
- Monitor for **clinically significant change** in a patient

Selecting Candidate Analytes: What are the causes of discrepant results?

Selecting Analytes		Special Considerations
Pre-analytical variation	• Patient misidentification - • Specimen related issues • Post- collection	Hematology
Analytical variation	• Instrument • Method	Point-of-Care Measurement Procedures
Biological variation	• Rhythmic changes • Lifespan • Treatment	Immunology and Molecular/Genetic Measurement Procedures
		Multiple Analyte Delta Checks

- Straseski J. The Delta Check in Action:Causes and consequences of discrepant laboratory results. ARUP Lab.
- CLSI. Use of Delta Checks in the Medical Laboratory. 1st ed. CLSI Guideline EP33. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Pre-analytical variation: Identification



Definition: Mislabeled

- Mislabeling errors are one of the most common pre-analytic errors in laboratory services, and they are usually detected by front end error checking by the laboratory or by automated delta checking.

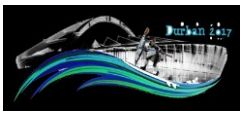
  72% of errors due to mislabeled specimens

  Arch Pathol Lab Med. 2010 Feb;134:244-55.

- JC National Patient Safety Goals:
  - Minimum two unique identifiers
  - Label samples in front of patients
- One or more identifiers are incorrect
  - Wrong patient label; tube label does not match paperwork or electronic order; contradictory labels on one tube
- Major problem in transfusion medicine
- Difficult to detect and assess – often go unreported

- https://www.jointcommission.org/lab_2017_npsgs/
- https://psnet.ahrq.gov/webmm/case/142

Pre-analytical variation: Identification



Definition: Misidentified

- Wrong blood in tube
- Possible causes
  - NICU, ER, geriatric populations
  - Sleeping, uncommunicative patients
  - Language barriers
  - Fraud
  - Identical names
  - Multiple births
- Majority of errors (10/17) associated with invasive procedures are due to patient misidentification
  Howanitz et al., Arch Pathol Lab Med 2002
- Misidentification errors occur in 0.04% to 1.0% of specimens.
  Arch Pathol Lab Med 2006, Arch Pathol Lab Med 2010, CLSI GP33-A
- Specimen misidentification can be reduced by use of advanced technological tools such as bedside bar-code identification of patients.

Pre-analytical variation: Identification

What are the analytes useful for detecting specimen misidentification?

Those ordered frequently within a short period of time (eg, daily). Some useful measurands/analytes for detecting misidentified specimens by delta checks are those on commonly used **chemistry and hematology panels**.

Pre-analytical variation: Identification

DE GRUYTER Clin Chem Lab Med 2016; 54(7): 1141–1145

EFLM Position Paper

Edmée C. van Dongen-Lases, Michael P. Cornes, Kjell Grankvist, Mercedes Ibarz, Gunn B.B. Kristensen, Giuseppe Lippi, Mads Nybo and Ana-Maria Simundic*, on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

Patient identification and tube labelling – a call for harmonisation

Clin Chem Lab Med 2016; 54(7): 1141–1145

Addresses **two of the most critical steps in phlebotomy:**

- tube labelling
- patient identification

DE GRUYTER Clin Chem Lab Med 2015; 53(3): 357–370

Opinion Paper

Giuseppe Lippi[a,*], Giuseppe Banfi, Stephen Church[a], Michael Cornes[a], Gabriella De Carli, Kjell Grankvist[a], Gunn B. Kristensen[a], Mercedes Ibarz[a], Mauro Panteghini, Mario Plebani, Mads Nybo[a], Stuart Smellie, Martina Zaninotto and Ana-Maria Simundic[a] on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase

Preanalytical quality improvement. In pursuit of harmony, on behalf of European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working group for Preanalytical Phase (WG-PRE)

Clin Chem Lab Med 2015; 53(3): 357–370

Presents evidence based approach for the management of preanalytical phase and **results of WG-PRE European Survey that identified to adapt the CLSI H3-A6 for training programs**

Pre-analytical variation: Collection

Source of Variation	Effect on Laboratory Result
IV Fluid dilution	False increase in corresponding analytes, dilution of other analytes
Serum vs plasma	Fibrinogen causes differences in total protein levels; clot formation causes release of K^+ from platelets; extremely high RBC counts increase K^+ from cell leakage
Order of blood tube collection	Contamination of subsequent tubes with anticoagulant, preservatives or other additives. Red top (non-additive) tube should be used as waste/discard tube
Improper anticoagulant	EDTA: increased K^+, decreased Ca^{+2}, Mg^{+2}, ALP
	Sodium citrate: increased Na^+, anion gap
	Heparin: inhibits PCR reactions
	Others: increase in predominant anticoagulant component
Long tourniquet time	Concentration of analytes, false increase in K^+, ammonia, lactate
Contrast agents	Some gadolinium agents falsely decrease Ca^{+2}
Serum separator tubes	Serum separator gel may absorb small molecules such as drugs. Red top tubes recommended for therapeutic drug monitoring and other drug levels.

Straseski J. The Delta Check in Action:Causes and consequences of discrepant laboratory results. ARUP Lab.

Pre-analytical variation: Post-Collection

- **Sample Transport:**
  - Timing: off-site blood drawing, delayed centrifugation, WBC glucose utilization, leakage of RBC contents
  - Temperature: Arterial blood gases, cryoglobulin, K^+, lactic acid, ammonia
  - Light exposure: bilirubin, Vitamins, porphyrins
  - Tube closure: pH, pCO_2, İca^{+2}, ACP, ethanol
  - Pneumatic tubes: may cause RBC damage
  - Hemolysis is masked in whole blood samples – spin to confirm
- **Centrifugation: Timely separation of serum and cells (w/i 2 hrs)**
  - Delayed separation affects glucose, K^+, LDH, ammonia, phosphate
  - Excessive spins: hemolysis due to RBC membrane damage; K^+, enzymes affected
- **Storage**
  - Labile analytes must be frozen, avoid excessive freeze-thaw cycles

What are the causes of discrepant results?

Pre-analytical variation	• **Patient misidentification –** at the time of phylebotomy or specimen labeling • **Specimen related issues** (eg, specimen contamination, inappropriate specimen handling, specimen interferences such as hemolysis, and inappropriate anticoagulants or preservatives) • **Post- collection**
Analytical variation	• **Instrument** • **Method**
Biological variation	• Rhythmic changes • Lifespan • Treatment

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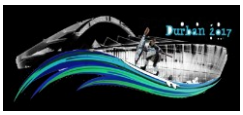
Analytical variation



- **Instrument-specific issues**
  - Reagent problems, variation in reagent volumes, delivery
  - Measurement procedure shifts or drifts,
  - Interinstrument differences – when more than one instrument is used for a measurand)
  - Probe or pipettor errors
  - Air bubbles
  - Calibration
- **Operator- or Method –specific issues**
  - Dilution errors, improper mixing
  - pH, temperature
  - Reagent, lot changes

This is where the majority of lab's investigative power lies (QC, imprecision, bias, etc.)

What are the causes of discrepant results?

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Biological variation

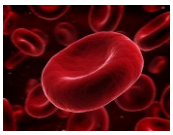
- The **components of BV** can be used to select measurands for detecting misidentified specimens.

Rhythmic changes	Lifespan	Treatment

• **Circadian** – Once per day – Cortisol, GH
• **Ultradian** - >Once per day – Pituitary, Hypothalamic h.
• **Infradian** - > One day – Menstrual cycle (FSH, LH)
• **Circannual** – Yearly – VitD, Cholesterol
	• Delta check limits may change w patient **age**
	  • MCV elevations in neonates
	  • Creat decreases w age, Urea increase w age
	• **Lifecycle changes** causes variation
	  • Nutritional status,
	  • Activity level
		• IV Fluids
		• Total parenteral nutrition (TPN; parenteral feeding)
		• Chemotherapeutics
		• Dialysis
		• Surgery
		• Organ Transplantation
		• Other medications

Special Considerations

Hematology



What values for hematology should have delta checks to prevent pre-analytical errors?

Analyte	Specimen Misidentification	Comment
Hematocrit	√	Low index of individuality*
Hemoglobin	√	Low index of individuality
MCH	√	Low index of individuality
MCV	√	Low index of individuality
MCHC	√	Low index of individuality
Platelet Count	√	Low index of individuality
WBC Count	√	Low index of individuality: most helpful for detecting specimen misidentification when one result is within and the other is outside the reference interval

MCV and MCHC – show the least short-term biological variability. Stable for 24 hr. In medical situations such as hemorrhage, MCV and MCHC do not change significantly since the reticulocyte response does not begin for two to three days.

MCHC has the added benefit of detecting instrument malfunction because it is calculated from hemoglobin, MCV and RBC count.

*) An Index of Individuality < 0.60 suggests the analyte is useful for delta checks for specimen misidentification

CLSI Guideline EP33, 2016; CAP TODAY, Dec.2006

Special Considerations

Point-of-Care Measurement Procedures

Analyte	Delta Check for POC measurement	Comment
Hemoglobin A1c, Cholesterol	Physician Office and Outpatient Clinics	Testing personnel should be familiar with the meaning of delta check alerts and how to respond them
Glucose, Hemoglobin A1c, Cholesterol, Coagulation tests	Problematic for several reasons	• Inherent differences in methodology trigger a large number of delta check alerts between the two results, and may not be clinically meaningful
		• Lab software would not consider different procedures
		• If POC results are not entered into the main LIS database or not done in real time, delta checks are likely to be no use
		• If data entry is performed by nonlab personnel, follow-up on delta checks needs to be considered

CLSI Guideline EP33, 2016

Special Considerations

Immunology and Molecular/Genetic Measurement Procedures

Analyte	Comment
ANA, Antihepatitis C virus antihepatitis B core or antihepatitis B surface antigen, antihuman immunodeficiency virus, syphilis serology or less commonly antigens eg. hepatitis B surface antigen	indicates misidentified specimens. Some antigens persist, such as chronic carriers of HBsAg. Same s true for molecular and genetic measurement, the higher cost makes it less likely that such procedures would be used for delta checks.

Multiple Analyte Delta Checks

Analyte	Comment
Urea and Creatinine or hemoglobin and hematocrit	These pairs physiologically correlated. Demonstrate positive correlation of delta checks. If only one of the pair is affected, a negative correlation of delta checks is flagged (eg, by the urea/creatinine ratio) indicating possible preexamination error.
AST and ALT, Total Protein and Albumin	Rules may be written into the LIS that identify these cases automatically. Also, to flag delta check alerts that are extremely different from previous results, such as 3X or greater than the established delta check limit

Lacher DA. Clin Chem. 1990;36(12):2134-6, CLSI Guideline EP33, 2016

Presentation Outline

- Definitions and Approaches to establishing delta check limits
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- **Developing rules for comparing them to previous results**
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What are the approaches to determine the limits used to signal a delta check alert?

Limits Derived from Biological Variation

- Sources of Variation in Laboratory Measurements
- Biological Variation
- Reference Change Values (RCV)

Limits Derived from Patient Data

- The Empirical Approach
- Delta Check Limits Derived from the Distribution of Delta Values in the Patient Population

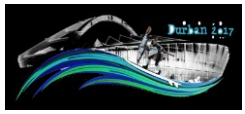
Time Interval Between Specimens, Rate Checks, and Clinically Significant Change

- Implementing Delta Checks in the LIS

Several approaches to setting delta check limits can be used, based on the purpose of delta check use in a laboratory.

- CLSI. Use of Delta Checks in the Medical Laboratory. 1st ed. CLSI Guideline EP33. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.
- Muller Journal of Medical Sciences and Research 8(1) Jan-June 2017, 42-6.

Biological Variation



To choose measurands that would be most useful to screen for misidentified specimens. Consists of:

Within-Subject biological variation*	**CV_I (I for individual)**	Normal fluctuation around an individual's homeostatic set point for a measurand over a period of hours, days, weeks, or longer.
Between-Subject biological variation	**CV_G (G for group)**	The variation among the homeostatic set points in the population.
Analytical variation of the measurement	**CV_A**	Represents the examination imprecision (from QC) relevant for the specimen being analyzed in the lab.
Index of Individuality	**$[CV_A^2 + CV_I^2]^{1/2}/ CV_G$** **$CV_I/CV_G$ (when $CV_A < 0.50\ CV_I$)**	The ratio of the combined **CV_I** and the measurement procedure imprecision (analytical imprecision) **CV_A** to the **CV_G** **<0.60 (high individuality)** = an individual's results normally stay within a narrow range compared with the population based ref.interval.

Fraser CG. Biological variation: from principles to practice. Washington DC. AACC Press ,2001
* Ricós C et al. Clin Chem 1994;40:472-477
* http:// www. Westgard.com/biodatabase1.htm
http:// www. seqc.es/es/Sociedad/51/102

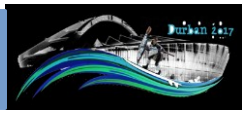
Creatinine 0.37 = low index of individuality; frequently measured; rapid changes expected in dialysis patients; change may indicate acute kidney injury.

Reference Change Value (RCV)

Is the difference between serial results (two values) statistically significant?

RCV=	**$2^{1/2} \bullet Z \bullet [CV_A^2 + CV_I^2]^{1/2}$**
	can be used to determine a delta check limit. Should be used for analytes with high individuality CV_I/CV_G < 0.6
Z scores	If the 2 results are statistically different from each other, the bidirectional Z-scores are used and pertinent in delta check limits for specimen misidentification. 1.96 for a 95% probability (significant) - autovalidation 2.58 for a 99% probability (highly significant) – manual verification
Question	Whether a second result higher (or lower) than the previous result? Unidirectional Z-zcores are needed. 1.65 for a 95% probability (significant) 2.33 for a 99% probability (highly significant)

Limits Derived from Patient Data



Should use lab data from own patient population and clinical location – dialysis clinic, transplant unit, etc.
3 approaches to set limits:

1. Empirical Approach

- Identify a goal of a detected failure
- What is to be identified – sample integrity, misidentified samples, changes in patient condition
- Some analytes more useful as delta checks:
  Little day-to-day variation
  Low RCV
  Low Index of Individuality
  Creatinine, ALP, Urea, Bilirubin, MCV

Logical Approach
- Keep a delta check log
- List the previous and current results that have delta check alerts
- Note about the outcome of the investigation

Limits Derived from Patient Data

Should use lab data from own patient population and clinical location – dialysis clinic, transpant unit, etc.
3 approaches to set limits:

2. From the Distribution of delta values in the patient population

It is possible to establish and refine delta check limits based upon patient data.
Delta check limits should be periodically evaluated to ensure the analytes selected and limits used are appropriate for the patient base and intended purpose of the delta checks

Practical Approach
- Download patient data for the analyte into a spreadsheet or statistical program
- Sort the data by patient name or medical record number
- Calculate the delta differences and time difference between consecutive results
- Limit the time between results
- Express the differences in whatever manner chosen – absolute, percentage, rate change

Limits Derived from Patient Data

Should use lab data from own patient population and clinical location – dialysis clinic, transpant unit, etc.
3 approaches to set limits:

3. Simulation of misidentified specimens

Practical Approach

- **Intentionally make the specimens mislabeled, contaminated, or otherwise compromised**
- **Analyze to see if delta check procedures gives an alert when a problem specimen is analyzed.**
- **Log this information**
- **Adjust the delta check limits periodically**

Clin Chim Acta. 2011;412(21-22):1973-77.

Time Interval Between Specimens

Example Delta Check Limits for some common analytes

Delta checks are recommended for inpatient testing. Generally, select chemistry analytes that have the lowest biological variation.

Measurand (Analyte)	Delta Limit
Albumin	2.0 g/dl
Bilirubin	2.0 mg/dl
*BUN	25 mg/dl
Calcium (Ca)	3.0 mg/dl
Carbon Dioxide	15 mEq/L
Chloride (Cl)	15 mEq/L
*Creatinine	1.0 mg/dl
Magnesium	2.0 mEq/L
Osmolality	20 mOsm/kg
Potassium (K)	2.5 mEq/L
Sodium (Na)	15 mEq/L
Total Protein	2.0 g/dl
**Uric Acid	2.0 mg/dl
MCV	5 fL
MCHC	5 g/dl

* Non-Renal
** Non-Heme/Onc

Time Frame

is the specimen collection time difference between the current and previous results.

- Time interval is flexible.
- Different percentages/absolute criteria may apply to different intervals
- Rate of change (eg, less than 5% change per day)
- To set the time interval slightly longer than one day, eg. 25 hours or 1500 minutes, or 2, 3 or more days.

Rate Checks

- Mostly **absolute rate of change** or **percentage rate of change**
- Percentage rate of change helpful for delta checking analytes that display large changes over time
- Useful to monitor some analytes for clinically significant change eg, PSA velocity

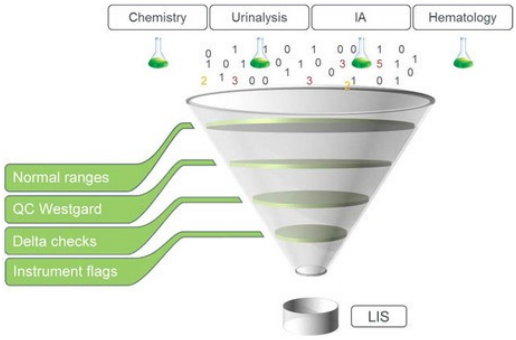
Clinically Significant Change

- **PSA velocity**
  - ≥ 2.0 ng/mL/year (≥ 2.0 µg/L/year)
  - Stated in terms of rate checks
  - Monitored on outpatients
- **Rate of Troponin rise indicative of an acute coronary event**
  - Various suggestions in the literature range from a 20% to a 50% rise from the previous result
  - Stated in terms of absolute or percentage absolute terms w/o specifying the time interval between specimens
  - Monitored on inpatients

Implementing Delta Checks in the LIS

3 basic types of rules are:

- Absolute differences in results
- Percentage differences in results
- Rate of change of results



Considerations for determination of delta check rules:

- **Time interval**
- **Expected minimum change during this time interval**, based on:
  - Qualitative change (eg.blood type, positive Ab to a negative result)
  - Absolute or percentage difference
  - The increasing and decreasing of differences
  - Varying rules depending upon whether the result is below, within or above the ref. interval or additional interval dependent constrains
  - Pathological state – chronic renal failure, chemotherapy,bone marrow transpant patients (change in AB0), patients of different physicians, marked changes in analyte values – cardiac markers after heart surgery, fall in serum proteins after transfusion of packed RBCs, rise in LD and fall in PLT and WBC count after chemotherapy
  - Hospital location, ordering physician, changes from ref intervals

Audience Response

Are delta checks used in the autoverification process?

1. **Yes**
2. **No**

Autoverification?

WHY

The delta check process was introduced as a quality control method to detect misidentified specimens. But with the rise in patient wristbands, barcode scanning, and improved patient identification, the frequency of mislabeled cups or tubes has drastically decreased in recent years.

The process of automated as opposed to manual delta checking became more useful with the rise in autoverification of results.

HOW

Should be specified with certain results for some analytes

Requires investment in personnel and training over the course of years.

Lastly, close collaboration between the clin lab and computing services is the key for ongoing success.

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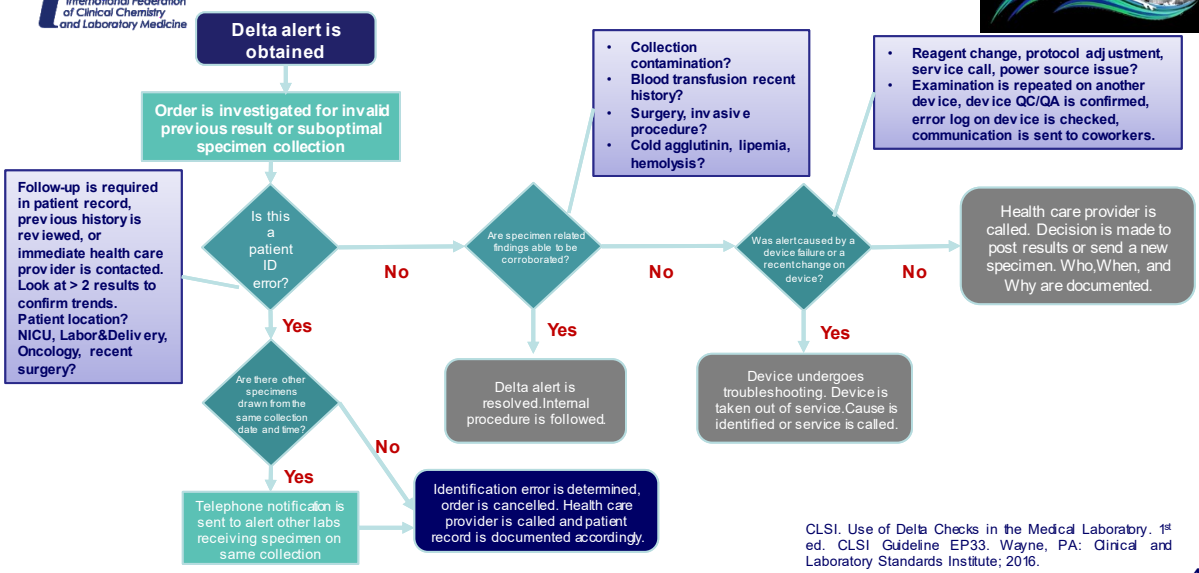
Investigating specimens with delta check alerts
Delta Check Alert Follow-up Flow Chart



CLSI. Use of Delta Checks in the Medical Laboratory. 1st ed. CLSI Guideline EP33. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Presentation Outline

- Definitions and Approaches to establishing delta check limits
- Selecting measurands for which delta checks are useful
- Developing rules for comparing them to previous results
- Investigating specimens with delta check alerts
- **Evaluating the effectiveness of the laboratory's delta check systems**

Evaluating the Effectiveness of Delta Checking After Implementation

- The majority of FP delta check alerts are due to real changes in patients' statuses. To exclude certain patients or wards from the delta analyses is advisable.

FP Results

- Refers to delta check alerts that do not identify the type of change of interest to the lab.
- Cost the lab time and effort to investigate insignificant changes in measured values
- Delay in reporting results, inappropriate treatment

TP results

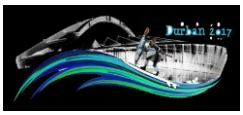
Indicates delta check alerts that were due to the causes of concern to the laboratory.

Performance of the delta check program

FN results

Indicate that a delta check alert did not occur when there was a specimen issue or patient condition change that should have been identified

Evaluating the Effectiveness of Delta Checking After Implementation



T1 Unit-Specific Cutoffs

	Renal cutoffs	Nonrenal cutoffs
BUN (mmol/L)	20	20
CA (mg/dl)	3	1.5
CR (mg/dl)	2.5	1
K (mmol/L)	3	1.5
NA (mmol/L)	10	10

BUN, blood urea nitrogen; CA, calcium; CR, creatinine; K, potassium; NA, sodium

T2 Unit-Matched and Mismatched Cutoffs

	No. of flags per 1000 test results
Renal unit (using renal cutoffs)	1.44
Nonrenal unit (using nonrenal cutoffs)	0.47
Renal unit (using nonrenal cutoffs)	2.88
Nonrenal unit (using renal cutoffs)	0.2

The key question that remains is

How do we best pick up specimen inaccuracies without an overwhelming number of false-positive delta check flags?

Optimizing cutoffs with lab-specific inputs

Experience at Santa Clara Valley Medical Center to establish unit-specific cutoff values.

To highlight the effect of different cutoffs for different units, they matched and mismatched unit- and renal- and nonrenal-specific cutoffs, respectively. Table illustrates how this remix affected the number of delta check flags per 1,000 test results. They found that using for nonrenal units the much tighter cutoff from renal units resulted in twice as many flags for renal unit patients.

Kampfrath, T. Clinical Laboratory News AUG.1.2017

Audience Response

Is the laboratory director required to approve all new and changed delta checks?

1. **Yes**
2. **No**

Lab Director

- Need to weigh the potential benefits against the potential time spent contacting clinicians and the potential that in many or most cases,
- He or she will already be aware of the change in patient status, especially with increasing use of the electronic medical record.

CLSI Guideline EP33, 2016

Audience Response

Are delta checks be reviewed for potential revision within last 3 years?

1. **Yes**
2. **No**

Delta Check Practices and Outcomes

A Q-Probes Study Involving 49 Health Care Facilities and 6541 Delta Check Alerts

Ron B. Schifman, MD; Michael Talbert, MD; Rhona J. Souers, MS

A total of 49 facilities participated in this study. Among 4505 testing episodes involving 6541 delta check alerts. Testing episode: action of collecting samples and perform several tests on them .

Table 3. Study Participants' Responses to Questionnaire About Delta Checks

Question	Responses, No. (%) Yes	No	Total
The laboratory director is required to approve all new and changed delta checks	37 (82.2)	8 (17.8)	45
The frequency of delta check events is monitored as part of quality assurance or other assessment process	19 (41.3)	27 (58.7)	46
The laboratory has written criteria describing specific actions required to handle delta check alerts	34 (75.6)	11 (24.4)	45
A checklist is used to handle delta check alerts	8 (17.4)	38 (82.6)	46
Delta checks are used in the autoverification process	34 (91.9)	3 (8.1)	37
Delta checks reviewed for potential revision within last 3 years	30 (65.2)	16 (34.8)	46

Summary

- Delta checks require high sensitivity and have been suggested to increase patient safety. Because a mislabeled specimen has the potential to cause serious harm; a delta check failure is treatable by investigating and/or canceling the test; and no patient harm results from a false positive delta check failure.
- Laboratories should identify their particular needs and customize their delta checking programs accordingly, considering their:
  - Purposes for delta checks
  - Prevalence of mislabeled specimens and other specimen problems
  - Patient population
- Consideration should be given to monitoring causes and outcomes of delta check alerts as part of the laboratory's overall performance improvement program.
- Multiple sources of error must be considered when determining delta check limits.

Useful Resources

- CLSI. Use of Delta Checks in the Medical Laboratory. 1st ed. CLSI Guideline EP33. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.
- https://www.westgard.com/biodatabase1.htm
- Ricos C, Alvarez V, Cava F, Garcia-Lario JV, Hernandez A, Jimenez CV, Minchinela J, Perich C, Simon M. "Current databases on biologic variation: pros, cons and progress." Scand J Clin Lab Invest 1999;59:491-500.
- Schifman R. et al. Delta Check Practices and Outcomes: A Q-Probes Study Involving 49 Health Care Facilities and 6541 Delta Check Alerts. Archives of pathology & laboratory medicine 141(6) · April 2017