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# The Role of Clinical Laboratory in Patient Safety

Faisal Ibrahim, MBA, MT(ASCP)
Director of Quality Assurance

# Learning Objectives

At the end of this talk the attendee will be able to:

- Discuss common pre analytical issues (collection tubes and patients identification)
- Discuss common referral laboratory issues
- Highlight common documents managements  shortfalls
- Recognise challenges with population reference ranges
- Apply continues survey readiness strategy
- Discuss challenges in POCTs

# Medical Errors – The third leading cause of death in the U.S

## Medical errors death ranges from 250,000 to 400,000



### Medical Errors Are Third Leading Cause of Death in the U.S.

10 percent of U.S. deaths are due to preventable medical mistakes.

By Steve Sternberg, Senior Writer | May 3, 2016, at 6:30 p.m.

**Healthcare of Tomorrow**

The health care industry is evolving, thanks to policy changes, societal shifts and technological advances. Healthcare of Tomorrow from U.S. News & World Report examines the challenges facing health care, and how it must change to face the future. See more U.S. News special reports.

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### Pre-Analytical Variation

**The Leading Cause of Error in Laboratory Medicine**

**Author:** Mahboobe Ghaedi, PhD, and Joe M. El-Khoury, PhD, DABCC, FACB // **Date:** JUL.1.2016 // **Source:** Clinical Laboratory News

**Topics:** Lab Management, Factors Affecting Test Results, Quality Assurance, Patient Safety

In a recent report, researchers from Johns Hopkins University School of Medicine in Baltimore made headlines when they estimated that medical error is the third leading cause of death in the U.S. (1). While patient safety remains a struggle in many areas of healthcare, laboratory medicine has been a leader in reducing error, with an estimated total error rate of 0.33%, the lowest in diagnostic medicine (2). Major advancements in automation and analytical instrumentation have helped reduce laboratory-associated errors over the last decade, but with pre-analytical errors currently accounting for up to 75% of all mistakes (3), laboratory medicine professionals must keep expanding their focus to what is happening outside of the lab.

The classic paradigm for a wider view of errors is the total testing process (TTP). Beginning with test ordering and ending with result reporting, TTP encompasses the pre-analytical, analytical, and post-analytical phases of testing (Figure 1). Pre-analytical variation includes all the steps that occur from test ordering until right before sample analysis. While the likelihood of variation in any of the three phases is not negligible, the vast majority of laboratory variation emerges from the many factors affecting laboratory specimens prior to testing. These activities include test ordering, patient preparation, specimen collection, transportation, preparation, and storage.

Since activities in the pre-analytical phase are neither performed entirely in the clinical laboratory nor under the control of laboratory personnel, they are harder to monitor and improve. Consequently, labs often have focused on improving areas under their direct control while leaving pre-analytical activities to healthcare professionals who have little to no formal training in laboratory medicine.

# Color Coding for Blood Collection Tube Closures

Clin Chem Lab Med. 2015 Feb;53(3):371-6. doi: 10.1515/cclm-2014-0927.

**Colour coding for blood collection tube closures - a call for harmonisation.**

Simundic AM, Cornes MP, Grankvist K, Lippi G, Nybo M, Ceriotti F, Theodorsson E, Panteghini M.

**Abstract**

At least one in 10 patients experience adverse events while receiving hospital care. Many of the errors are related to laboratory diagnostics. Efforts to reduce laboratory errors over recent decades have primarily focused on the measurement process while pre- and post-analytical errors including errors in sampling, reporting and decision-making have received much less attention. Proper sampling and additives to the samples are essential. Tubes and additives are identified not only in writing on the tubes but also by the colour of the tube closures. Unfortunately these colours have not been standardised, running the risk of error when tubes from one manufacturer are replaced by the tubes from another manufacturer that use different colour coding. EFLM therefore supports the worldwide harmonisation of the colour coding for blood collection tube closures and labels in order to reduce the risk of pre-analytical errors and improve the patient safety.

PMID: 25324449 DOI: 10.1515/cclm-2014-0927

EFLM TFG-STCC Proposal for the color coding standard of the blood tube closures

| Specimen type | Additive | ISO 4822 (1981) ≠ | BS 4851 (1982) | ISO 6710 (1995) | CLSI H1-A5 (2003) | CLSI GP41-A6* (2007) | Swedish standard SS-872805 (2011) | EFLM proposal (color) |
|---|---|---|---|---|---|---|---|---|
| Serum | Clot activator | Z (no additive) | White (no additive) | Red | Red | Red | Red | |
| Serum with gel | Gel, clot activator | NA | NA | NA | NA | Red | Yellow | |
| Plasma | Heparin | LH (Li- heparin) NH (Na-heparin) | Orange (Li-heparin) Brown (Na-heparin) | Green | Green | Green | Light green | |
| Plasma with gel | Gel, heparin | NA | NA | NA | NA | Green | Dark green | |
| Plasma | Citrate (1:9) | 9 NC | Indigo | Light blue | Blue | Blue | Light blue | |
| Whole blood | Citrate (1:4) | 4 NC | Mauve | Black | Black | NA | Black | |
| Whole blood | EDTA | KE (K salt) LE (Lithium salt) NE (Sodium salt) | Pink | Lavender | Lavender | Lavender or Pearl | Lavender | |
| Plasma EDTA with gel | Gel, EDTA | NA | NA | NA | NA | Lavender or Pearl | White or pearl | |
| Plasma | Glycolytic inhibitor | FX | Yellow | Grey | Grey | Grey | Grey | |

*≠ - ISO 4822 standard had suggested a letter coding for different anticoagulants (the standard did not contain color coding proposal)*
** - (former H03-A6)*


"OK, the old one's in my right hand, the donor's in my left. Right?"

# Specimen misidentification

- Despite advance in health care technology, medical mistakes from patient and specimen misidentification continue to occur
- Between 2007 and 2015, the use of bar-code systems in healthcare environment increase from 8% to 38% , yet the rate of “wrong blood in tube” didn’t decrease
- Up to 1% of collection tubes are mislabelled
- 7.4% of patient ID bands are missing or contains erroneous information
- 11% of transfusion death occurs because the healthcare professional didn’t properly identified the patient or mislabelled the tube of blood

Technology alone will not eliminate patient ID specimen labelling errors. Therefore, standardized process with rigid adherence, regular audits, and consequences for noncompliance are necessary  to fully protect the public

*CLSI. Accuracy in Patient and Specimen Identification*. 2nd ed. CLSI Standard GP33

# The laboratory role in specimen misidentification

Delta checks:

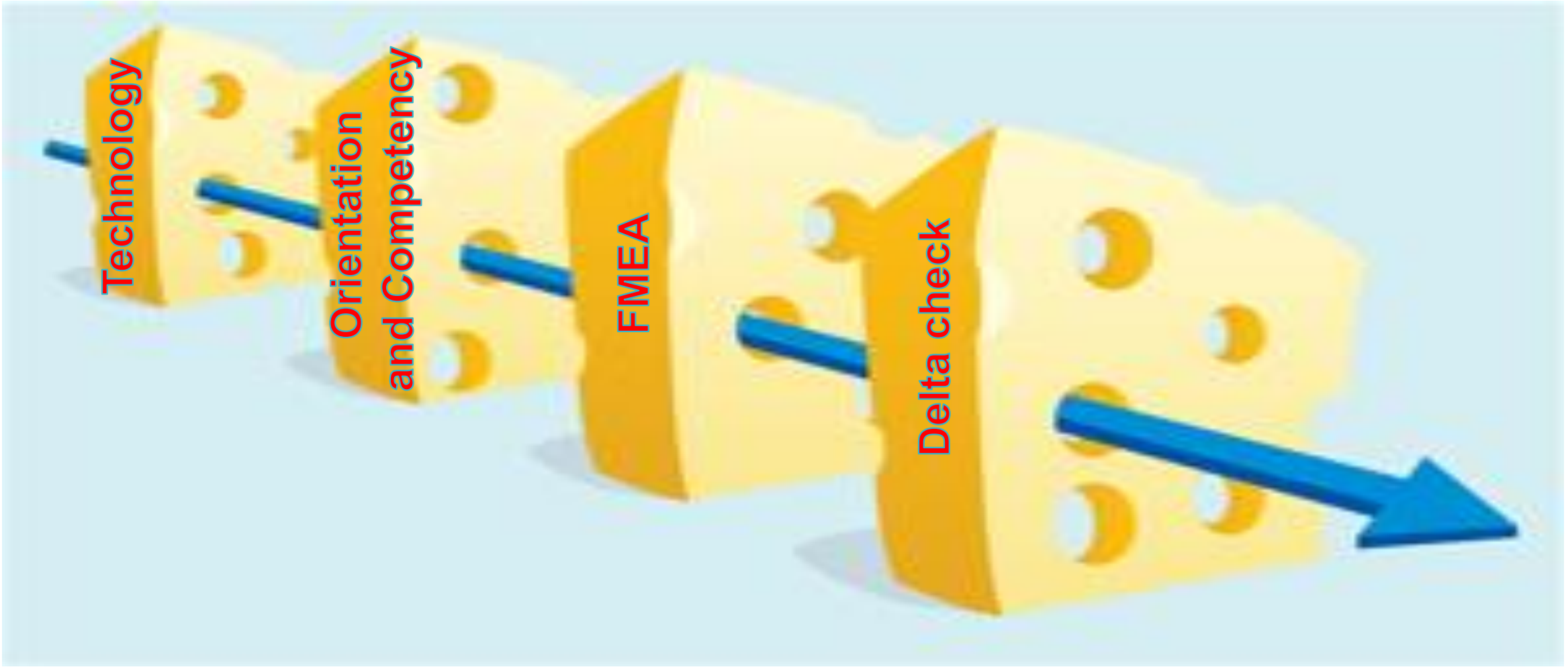
Clinically inexplicable results and results that are vastly different from the patient's previous results.

Examples of examinations suitable for delta checks used in the laboratory are:

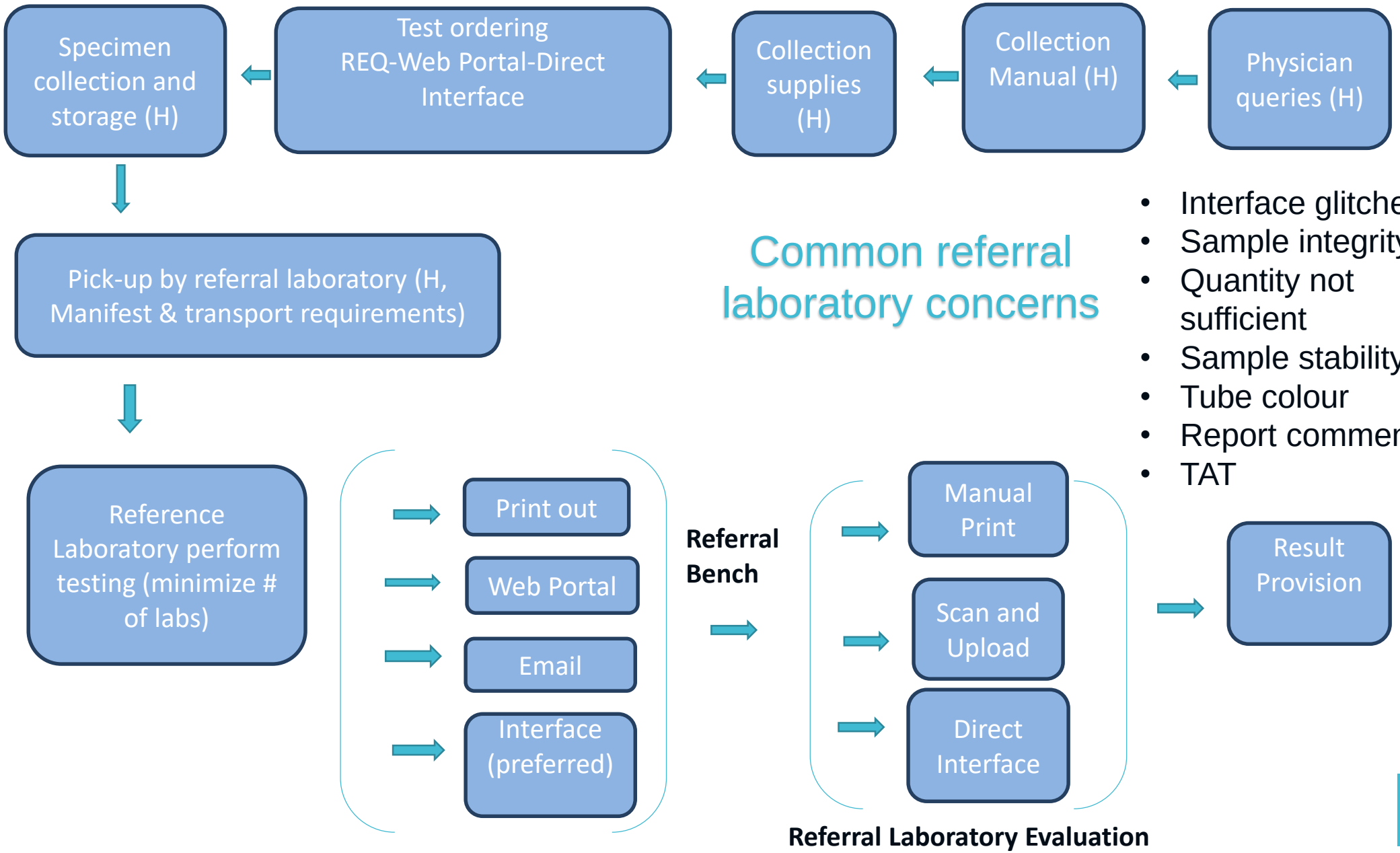
- Blood type
- Erythrocyte mean cell volume
- Total protein
- Albumin
- Haemoglobin
- ALT and AST

The time interval over which a delta check criterion  is to be applied must be specified in relevant procedures

# The laboratory role in specimen misidentification



# Referral Laboratory Testing




## Common referral laboratory concerns

- Interface glitches
- Sample integrity
- Quantity not sufficient
- Sample stability
- Tube colour
- Report comments
- TAT

# Evaluating a Referral Laboratory

Commonly used documents for compliance

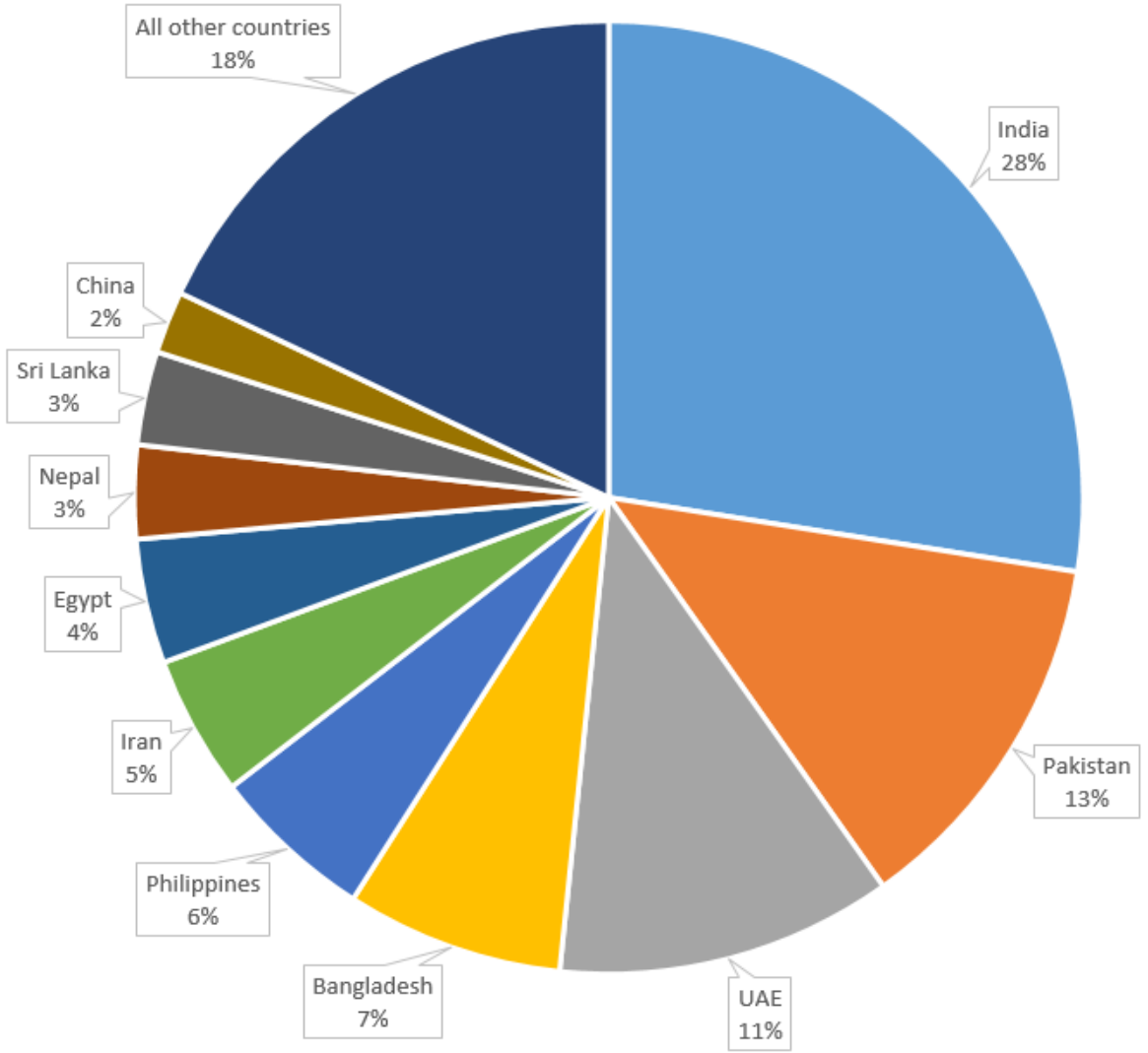
| CAP | ISO15189 | JCI | Local regulations | Remarks if any |
|---|---|---|---|---|
| Referral Lab Evaluation should be reviewed and signed by Medical Director | Referral Lab Evaluation form, reviewed and signed by Medical Director | Referral Lab Evaluation form, reviewed and signed by Medical Director | Referral Lab Evaluation form, reviewed and signed by Medical Director | |
| Facility License Copy Accreditation Certificate | Facility License Copy Accreditation Certificate | Facility License Copy Accreditation Certificate | Facility License Copy Accreditation Certificate | |
| Proficiency testing score cards | Proficiency testing score cads | Proficiency testing score cads | Proficiency testing score cads | |
| Annual approved Referral lab list with scope of referrals | Annual approved Referral lab list with scope of referrals | Annual approved Referral lab list with scope of referrals | Annual approved Referral lab list with scope of referrals | |
| - | - | Credential evaluation (if needed) this has to be prepared by the Hospital team | - | |
| CAP Checklist GEN.41350 | ISO 15189 Standard : 4.5 | JCI Standard GLD.2.2 | | |

# Standard Operating Procedure

- The use of standardized SOP across the health system network is recommended
- Use one set of Administrative SOPs (whenever possible)
- Use the same SOP template
- Special attention to interdepartmental SOPs:
  - Transfusion Medicine (i.e., transfusion reaction)
  - POCT (i.e., governance, training, competency, instrument maintenance, QC)
  - Safety (laboratory, Hospital, occupational health)
  - Critical results reporting

# Reference intervals

# UAE POPULATION BY NATIONALITY 2016

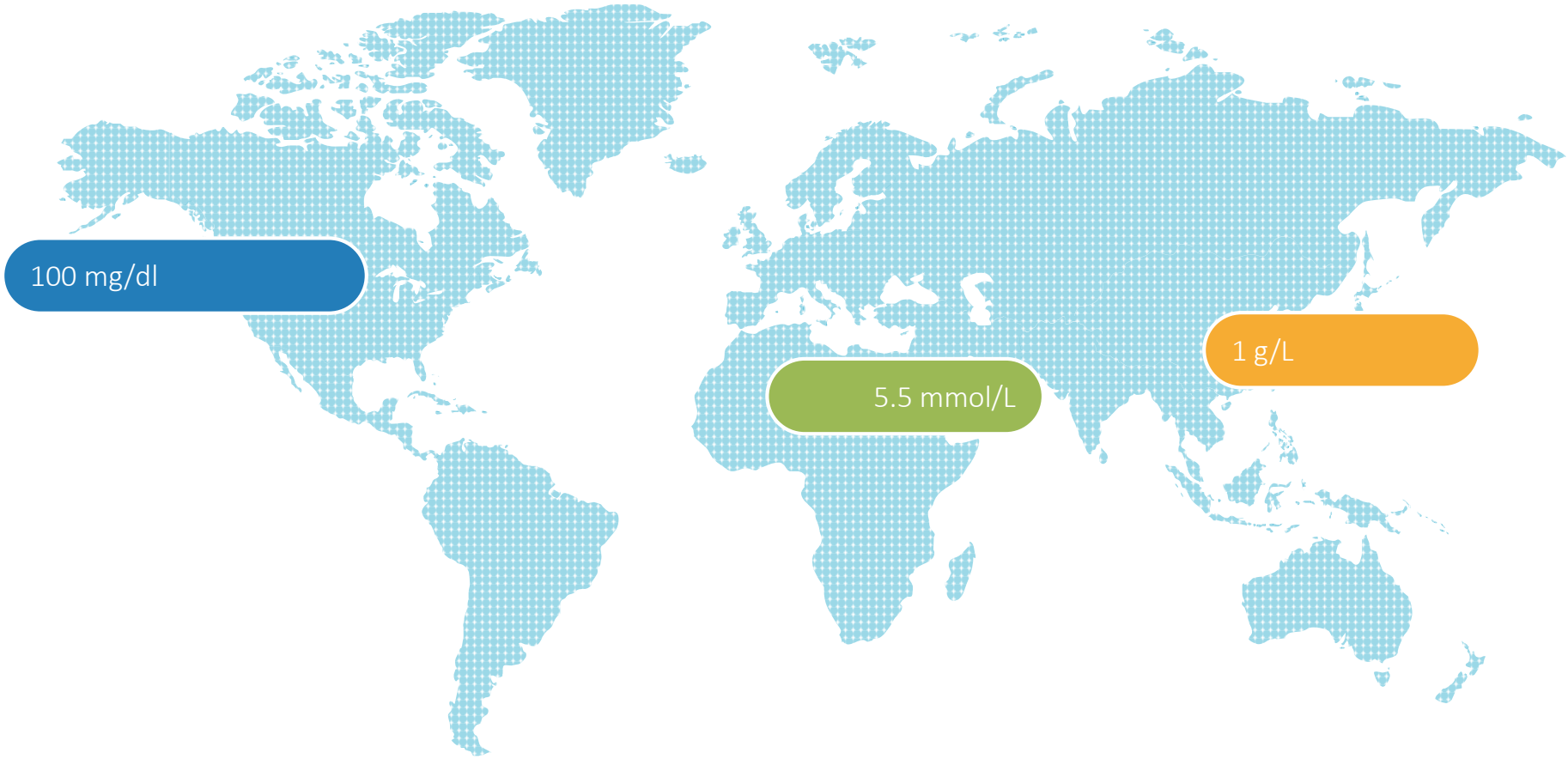



https://www.google.com/search?q=uae+population+by+nationality&source=lnms&tbm=isch&sa=X&ved=0ahUKEwibgeHl9Y3gAhVPVhoKHYhtBBAQ_AUIDigB&biw=1097&bih=527#imgrc=uCIXwJ9YNkIH-M:&spf=1548590669570

# Reference Range

- Kit insert
- Referral laboratory
- Review patients population from LIS
- Age
- Publications
- Gender

# Units of Measurements – Glucose



# EVOLUTION OF INTERNAL AUDITS AT NRL

## Continuous survey readiness

The QA Department is adapting a Continue Survey Readiness (CSR) module to ensure that all NRL laboratories are well prepared for any unannounced inspections either by local or international surveyors. Also, to ensure quality is maintained throughout the year A variety of approaches and learning methods were used including:

- Face-to-face education with front-line staff
- Resource folders with latest accreditation standards and elements of compliance
- Monthly QA verification to all laboratories
- Group lectures
- Mock surveys to assess compliance with standards

**2016** Monthly QA Audit across the network which consist of reviewing QC records, PT, equipment maintenance, safety, etc

**2017** Inspection readiness and verification checklist (checklist to assist staff with inspection preparation)

**2018** The addition of the ISO 15189 Standard to the monthly QA Audit (ISO 15189 is assessed throughout the year)

**2019** Started to conduct biannual audits to the non-technical departments (IT, SCM, HR, Finance, etc.)

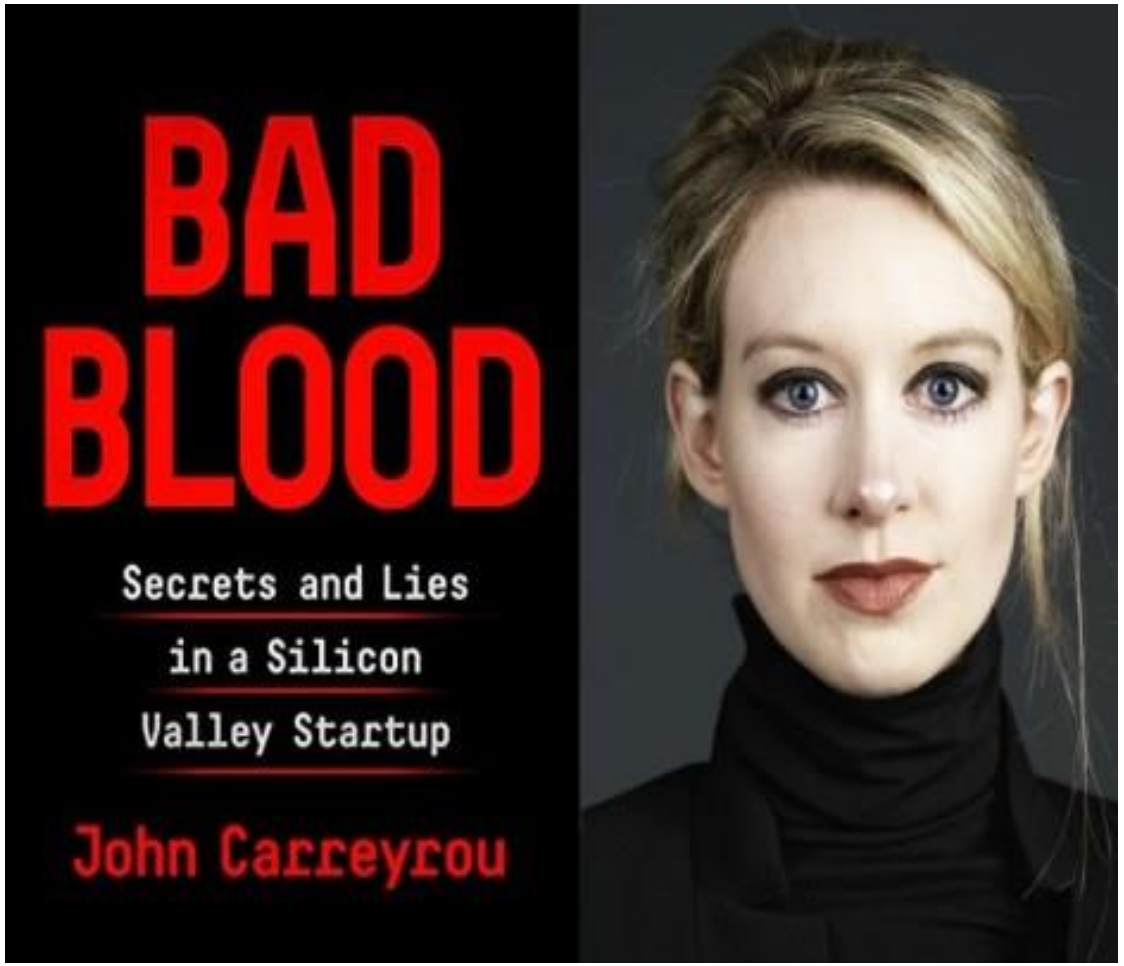
**2020** The addition of process specific audit to ensure compliance and improve efficiency (i.e. QC, specimen receiving, etc.)

# POCT challenges

- Dozens of sites
- Hundreds of devices
- Thousands of operators
- Instruments verification
- Pre-analytical variables
- Maintenance requirements
- QC requirements

# Theranos

- Founded in 2003 by Elizabeth Homes.
- Hand-held device took a minute amount of blood and tested for range of diseases
- 2010 value at more than $1 billion
- 2013 - Partner with a major drug stores company in the U.S to offer tests in store in more than 40 locations
- 2016 – The End



# Achieving excellence in POCT

- Don’t just add tests because they are available
- Stick to one vendor or one type of device
- Standardize training; check competence
- Minimize the number of POCT staff
- Centralize POCT management
- Have laboratory select and validate instruments
- Don’t let clinicians dictate POC tests

# Summary

- Pre-analytical issues (collection tubes and patients identification)
- Common referral laboratory issues
- Documents managements  shortfalls
- Reference ranges
- Apply continues survey readiness strategy
- Challenges in POCTs

# References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