The Association for Clinical Biochemistry and Laboratory Medicine

Better Science, Better Testing, Better Care

ACB National Audit: Specimen Contamination

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Deacon's Challenge

No 115 - Answer

Calculate the measured plasma sodium concentration if blood with a true plasma sodium concentration of 140 mmol/L is mistakenly drawn into an 'anticoagulation' Vacutainer tube.

These tubes originally contain 0.5 mL trisodium citrate solution (citrate concentration 0.105 mol/L) and the final volume of anticoagulated blood is 4.5 mL. You may assume that the sodium measurement is analytically correct.

FRCPath, Spring 2010

Background

- Pre-analytical issues may be an underappreciated source of poor patient experience
- The prevalence of sample contamination with EDTA or drip arm and/or poor sample quality (*e.g.* excessive haemolysis) is anecdotally increasing
- Patient safety may be compromised by delay or misleading results if changes are subtle: *e.g.* a genuinely low K is pushed into the normal range or a genuinely normal K appears elevated due to EDTA contamination

Background

- Repeat blood sampling is also frustrating for patients and clinical teams and is a significant waste of ward and laboratory resources
- Contaminated samples may have been collected at a time that renders them unrepeatable and a critical diagnostic (*e.g.* hypoglycaemia) or therapy monitoring (*e.g.* drug levels) opportunity may be lost
- Further, they may require an urgent visit to hospital for an urgent repeat sample, causing significant patient, parent/carer anxiety

Case

- Female, 35yrs, seen by GP, “fatigue, known hypothyroidism”
- 4 tubes: 1) U/Es, LFTs, TFTs; 2) Glu; 3) FBC; 4) ESR
- Received by lab at 16.47, 23rd Aug
- U/Es processed at 18:16
- Na 159 (RR 135-145 mmol/L) phoned to unscheduled care at 19:55 by BMS (Note: no recent previous results)
- Patient brought in to A+E that night, repeat bloods taken, Na 138, patient sent home
- Impression: “spurious blood test result”
- Results awaiting clinical authorisation by DB, AM 24th
- Cl and osmo added:
  - Cl 86 (RR 95-107 mmol/L)
  - Osmo 280 (RR 280-296 mosm/Kg)
- Conclusion: Trisodium citrate contamination from ESR tube

Background

- These problems apply to all patients but may be particularly acute in paediatrics where needle-phobia and patient co-operation with sample collection are major issues
- The objectives of this audit were:
  1. To establish the nature and scale of the problems
  2. To suggest possible solutions to improve patient safety and experience

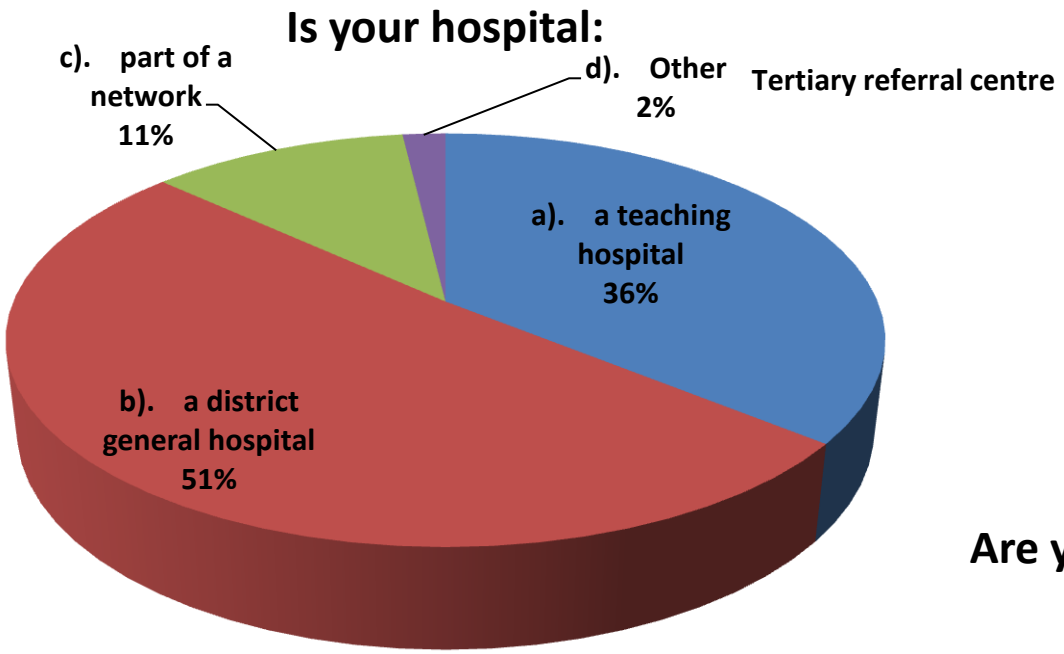
Methods

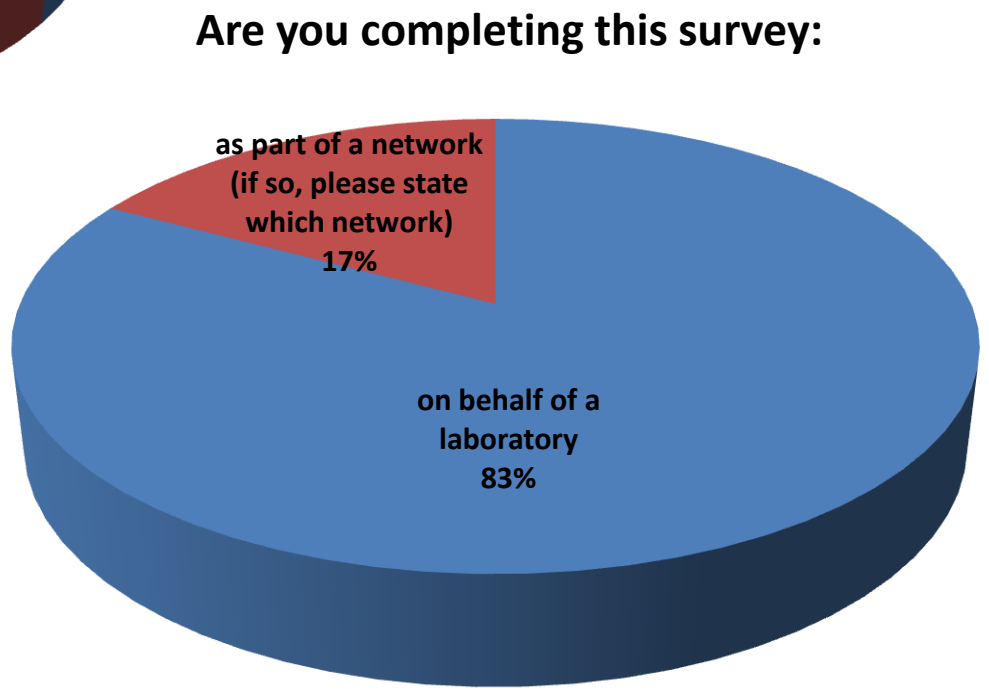
- SurveyMonkey®
- Distributed 23rd January 2017
- Closed 13th March 2017
- Link sent to 353 ACB members (Head of department or most senior staff, by job title)
- 52 responses, a large proportion ‘partial’
- Data analysis in Microsoft® Excel® 2007 & Analyse-it®

Layout & content

- Patient demographics
- Workload
- Venipuncture
- Blood tubes
- Contamination
  - *General*
  - *Drip arm contamination*
  - *EDTA contamination*
  - *Citrate contamination*
- Results reporting
- Risk management

Respondents

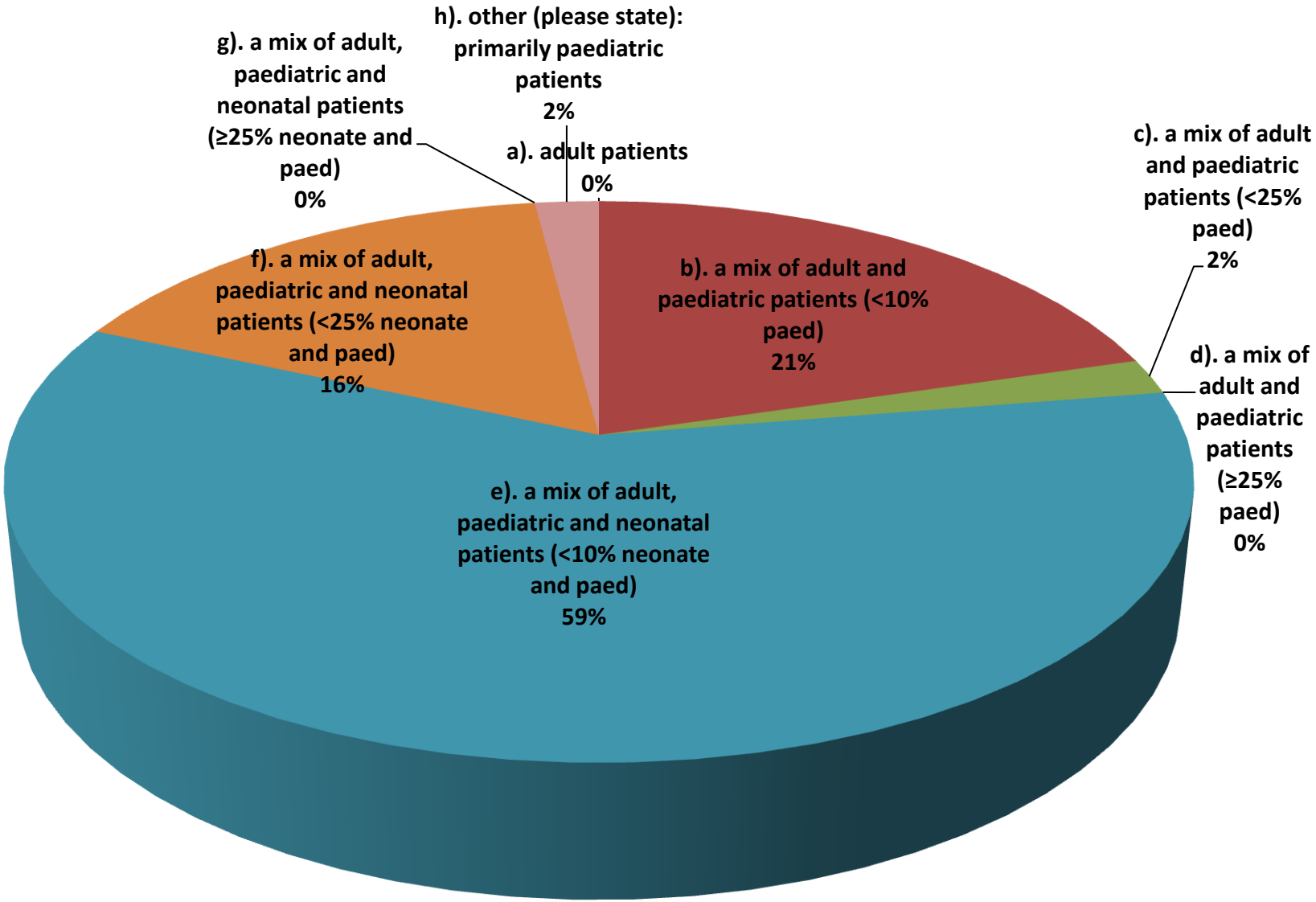




Q1

Patient demographics

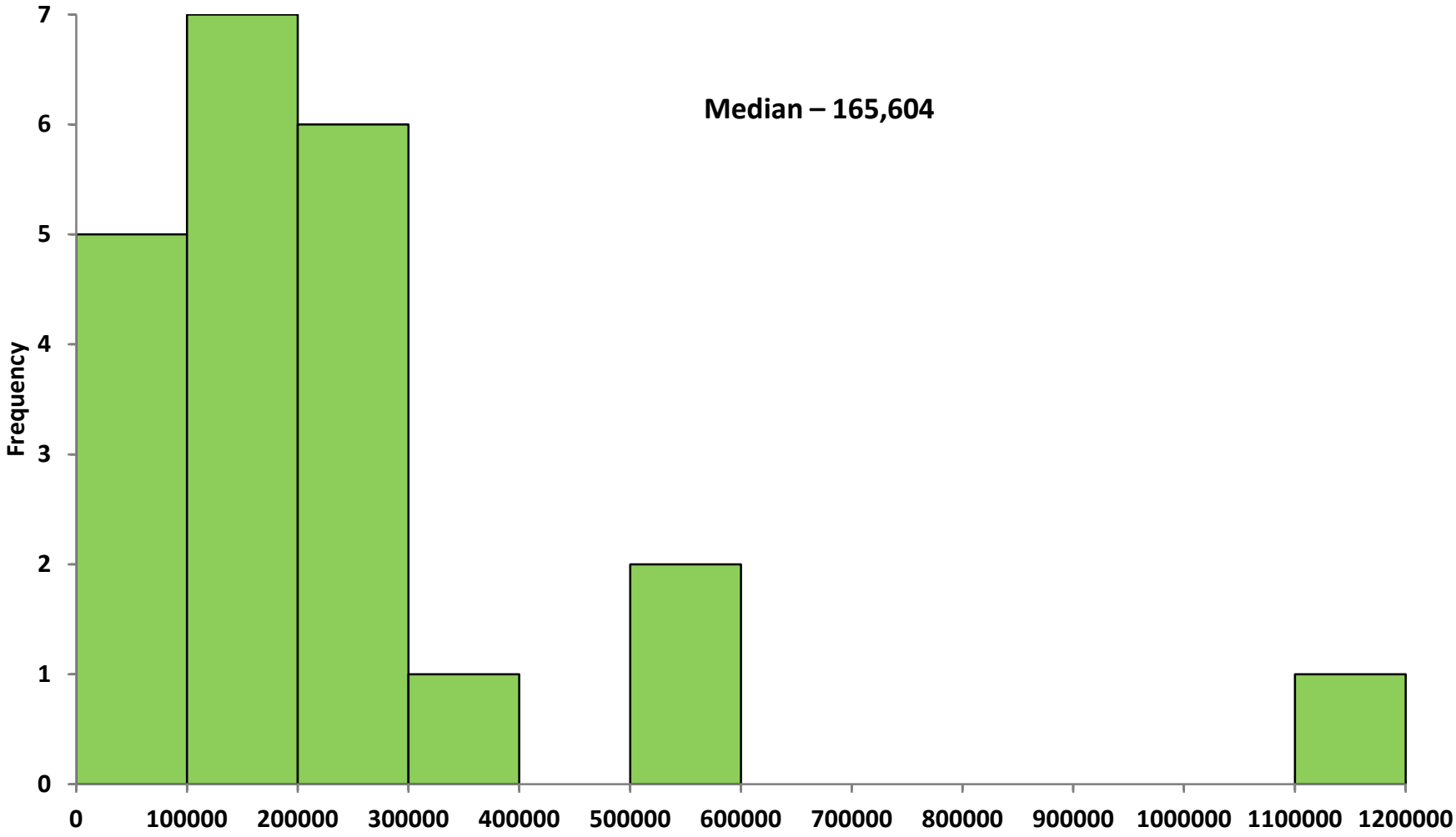
Does your laboratory primarily serve:
(adult: ≥18y; paediatric: 29d-17y11mo; neonatal: 0-28d)



Q2

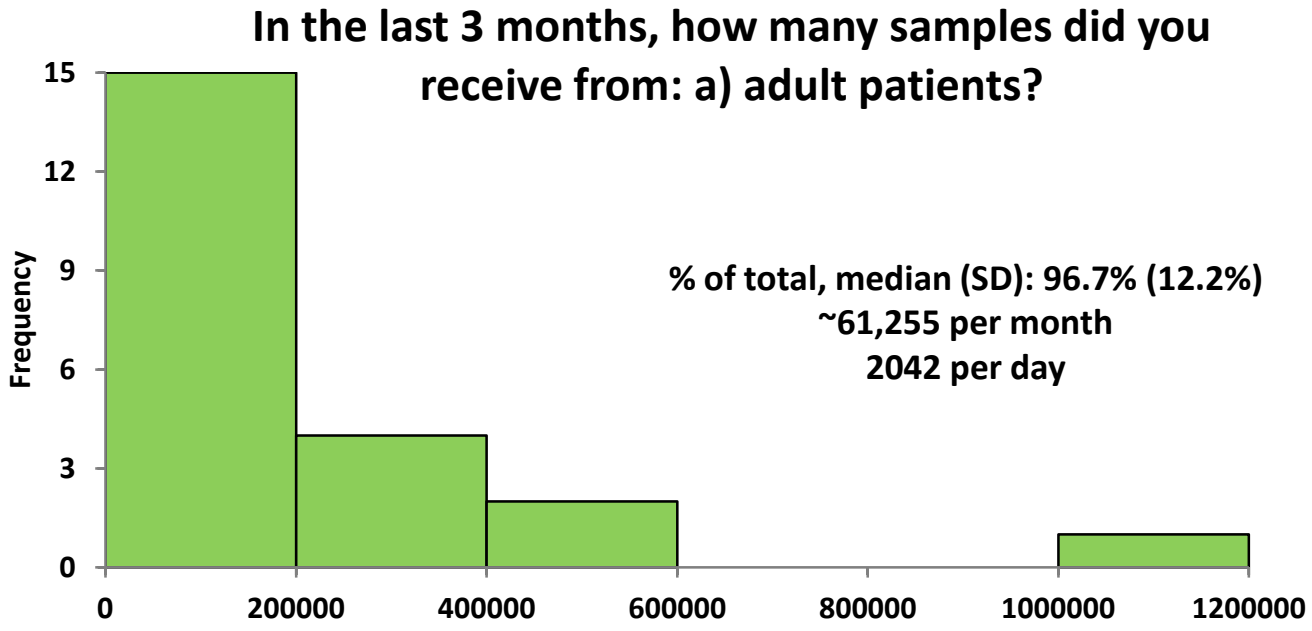
Workload

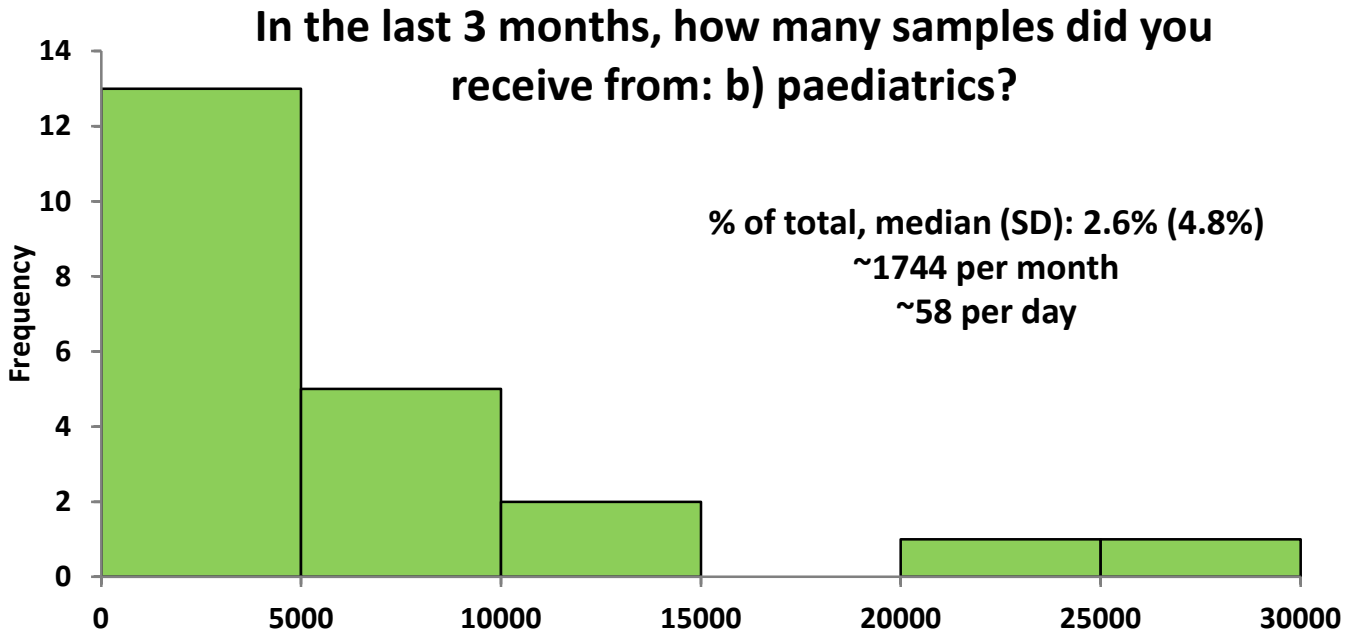
How many samples did you receive in total in the last 3 months?



Q3

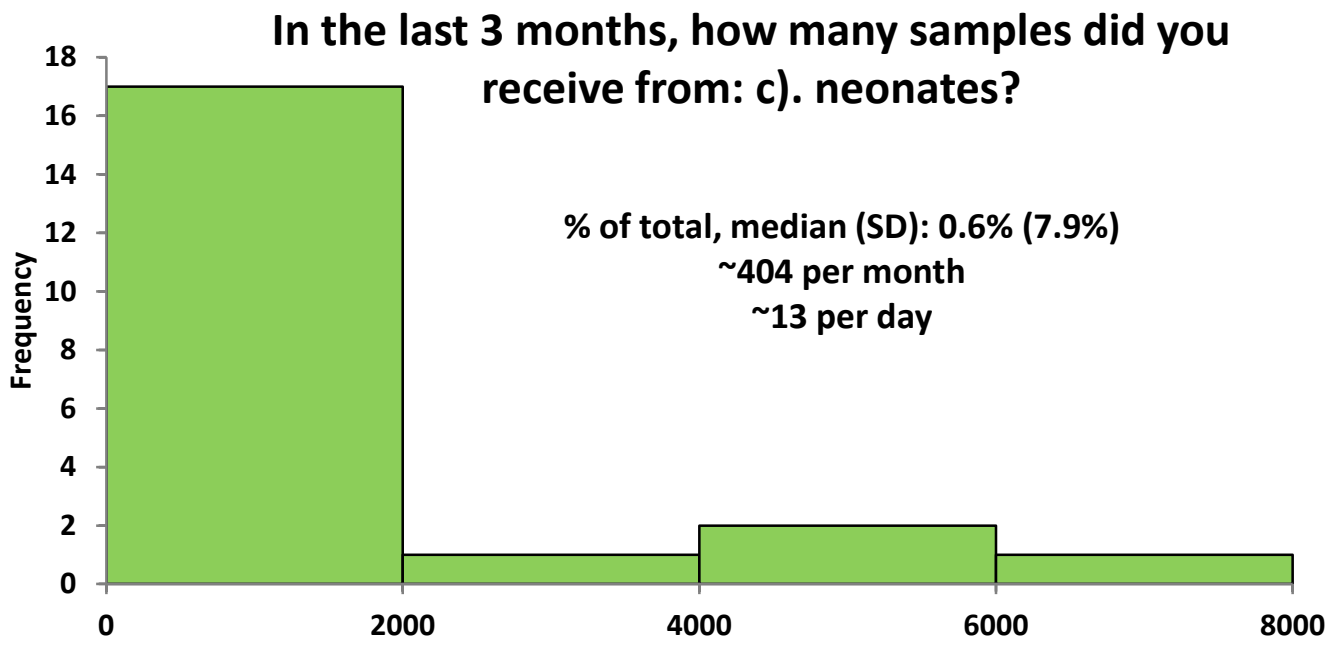
Workload


In the last 3 months, how many samples did you receive from: a) adult patients?
Frequency
15
12
9
6
3
0
0
200000
400000
600000
800000
1000000
1200000
% of total, median (SD): 96.7% (12.2%)
~61,255 per month
2042 per day


In the last 3 months, how many samples did you receive from: b) paediatrics?
Frequency
14
12
10
8
6
4
2
0
0
5000
10000
15000
20000
25000
30000
% of total, median (SD): 2.6% (4.8%)
~1744 per month
~58 per day

Q3

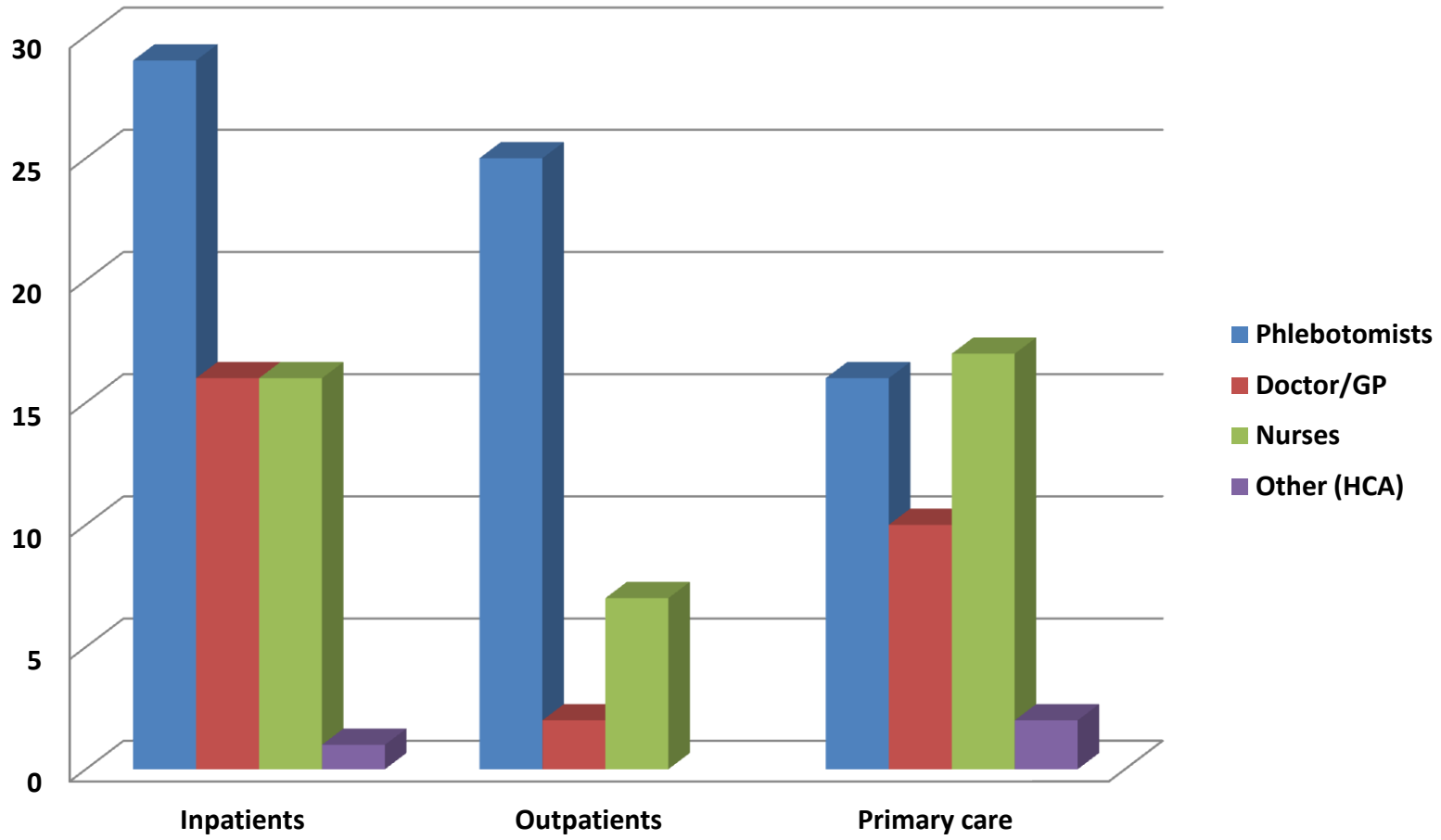
Workload


In the last 3 months, how many samples did you receive from: c). neonates?
% of total, median (SD): 0.6% (7.9%)
~404 per month
~13 per day
Frequency
18
16
14
12
10
8
6
4
2
0
0
2000
4000
6000
8000

Q4

Venipuncture

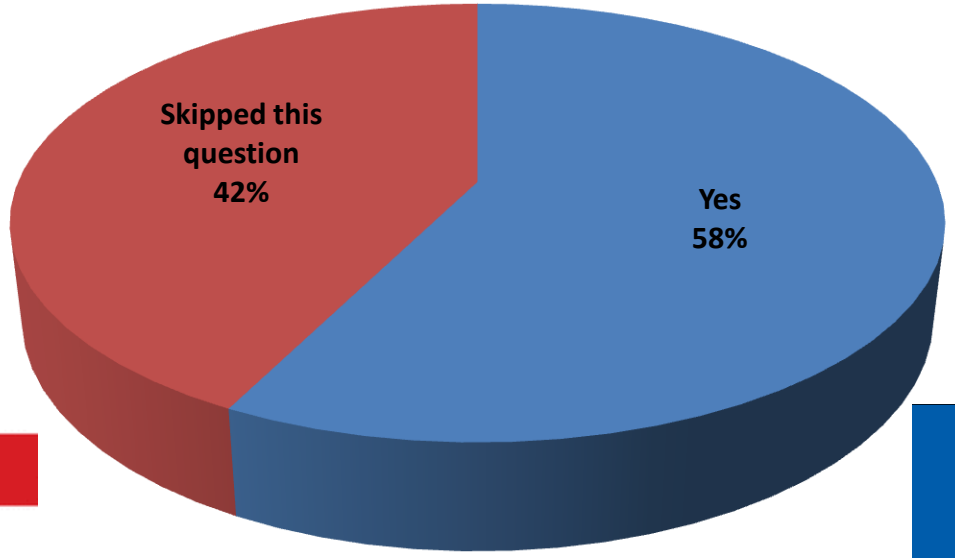
Which staff group mainly performs venipuncture for samples sent to your laboratory?

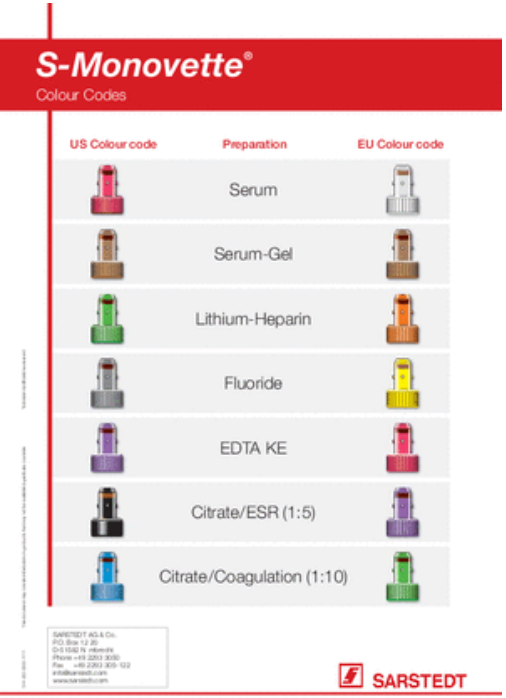


Q5

Venipuncture

Do staff performing venipuncture follow an 'order of draw' list from the tube manufacturer?

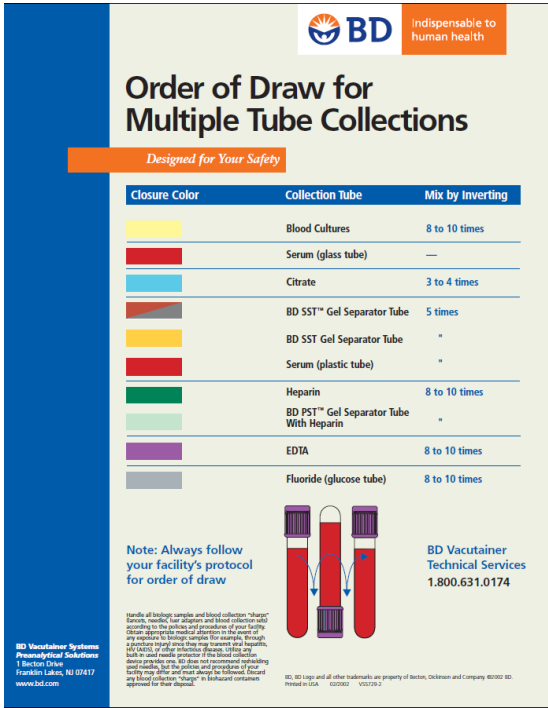




Opinion Paper

Michael Cornes*, Edmée van Dongen-Lases, Kjell Grankvist, Mercedes Ibarz, Gunn 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)

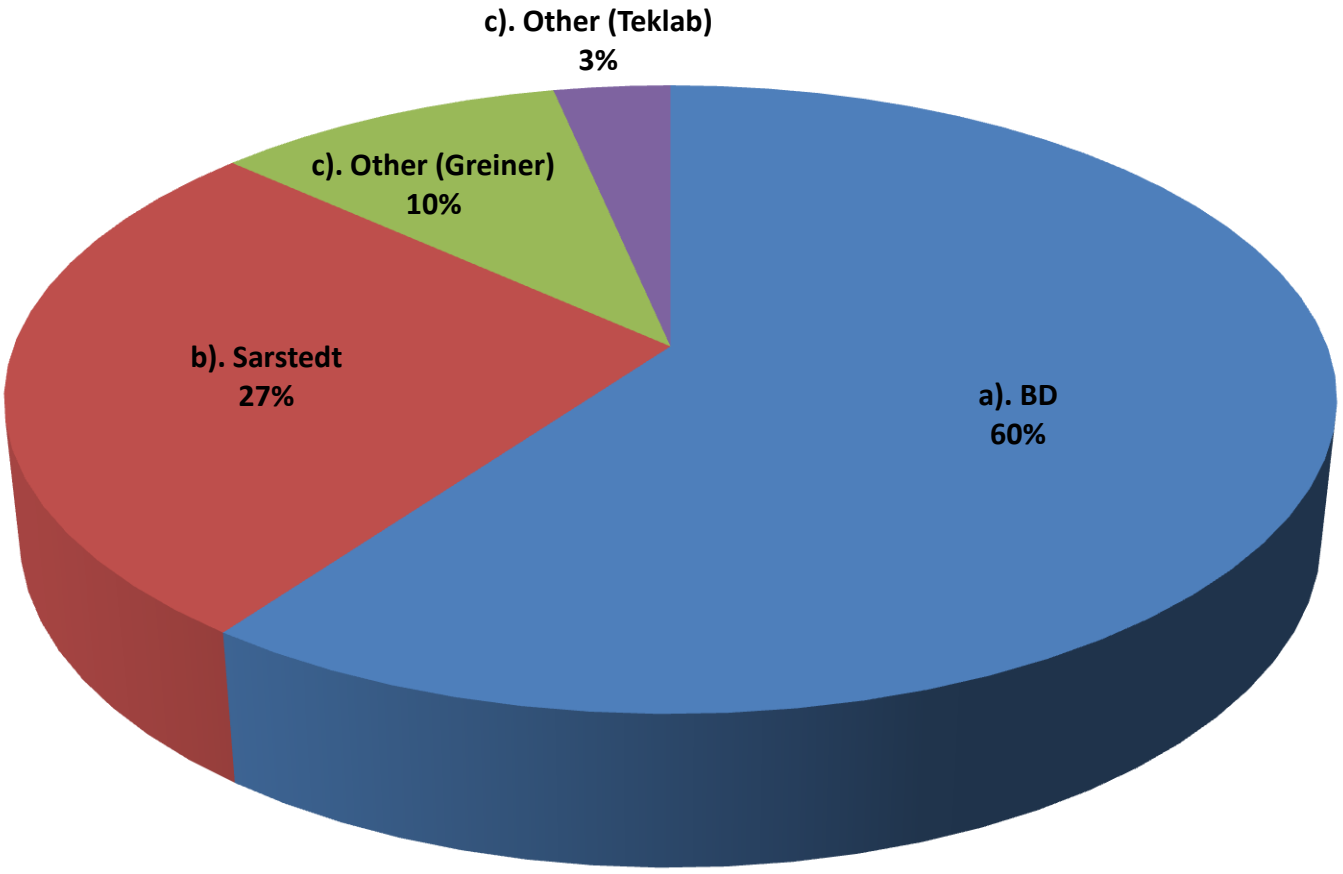
Order of blood draw: Opinion Paper by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE)



Q6

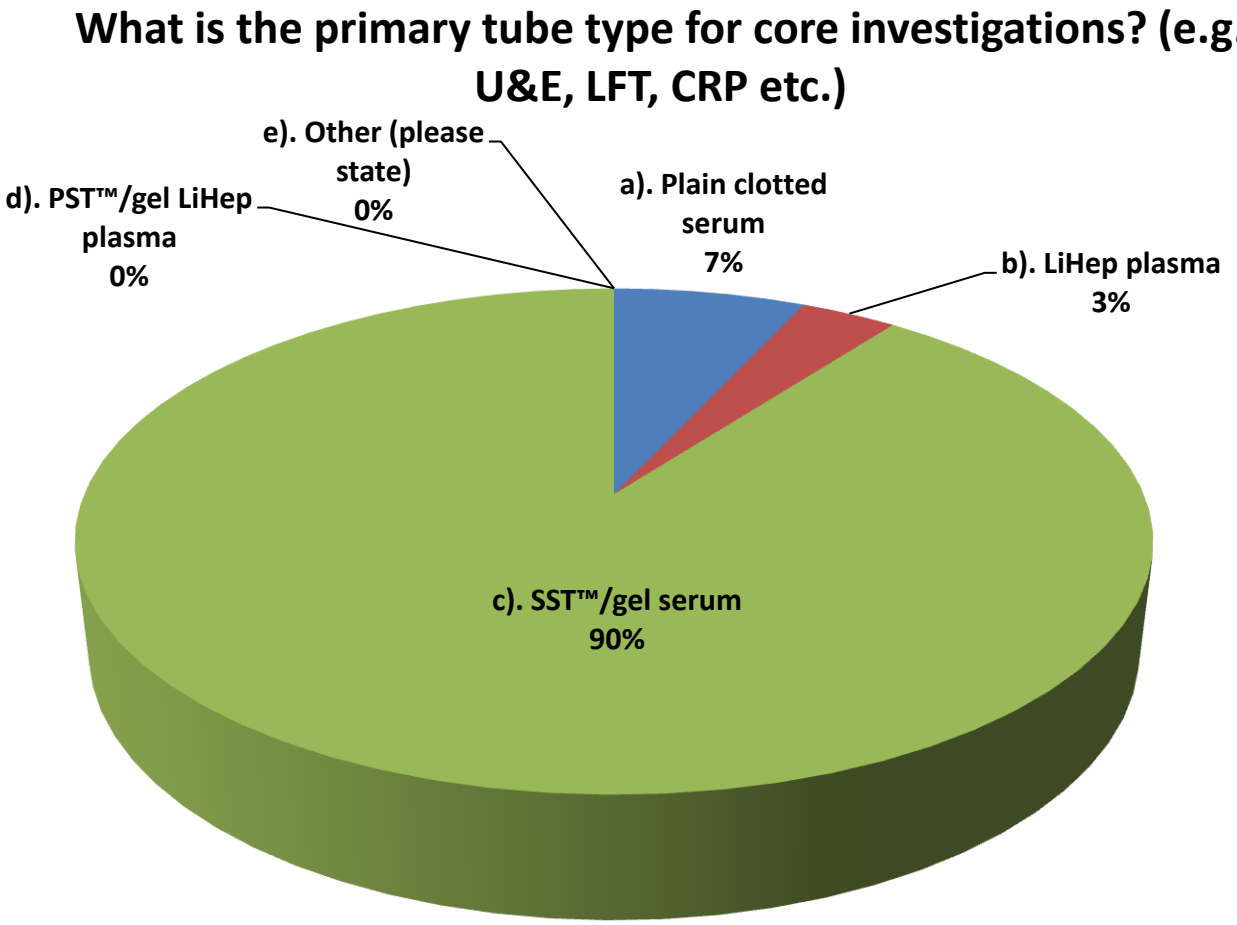
Blood tubes

Who is your main blood tube manufacturer?



Q7

Blood tubes

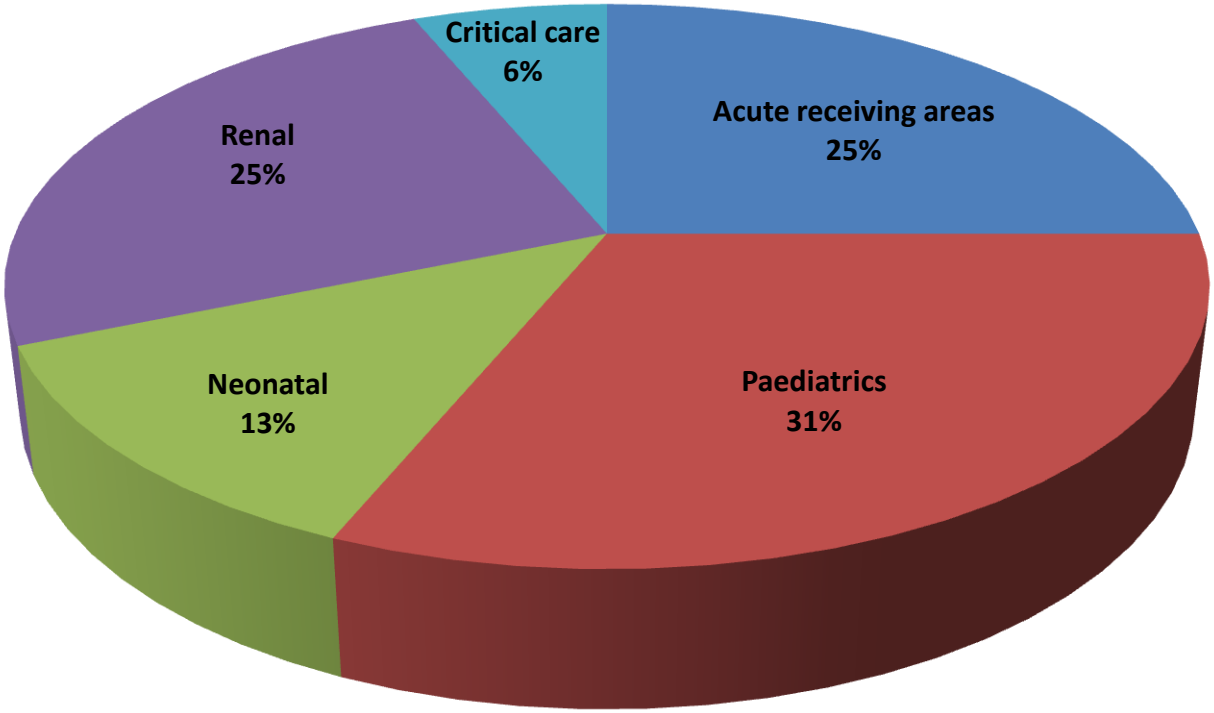


Q7

Blood tubes

If this differs by location, please give details.

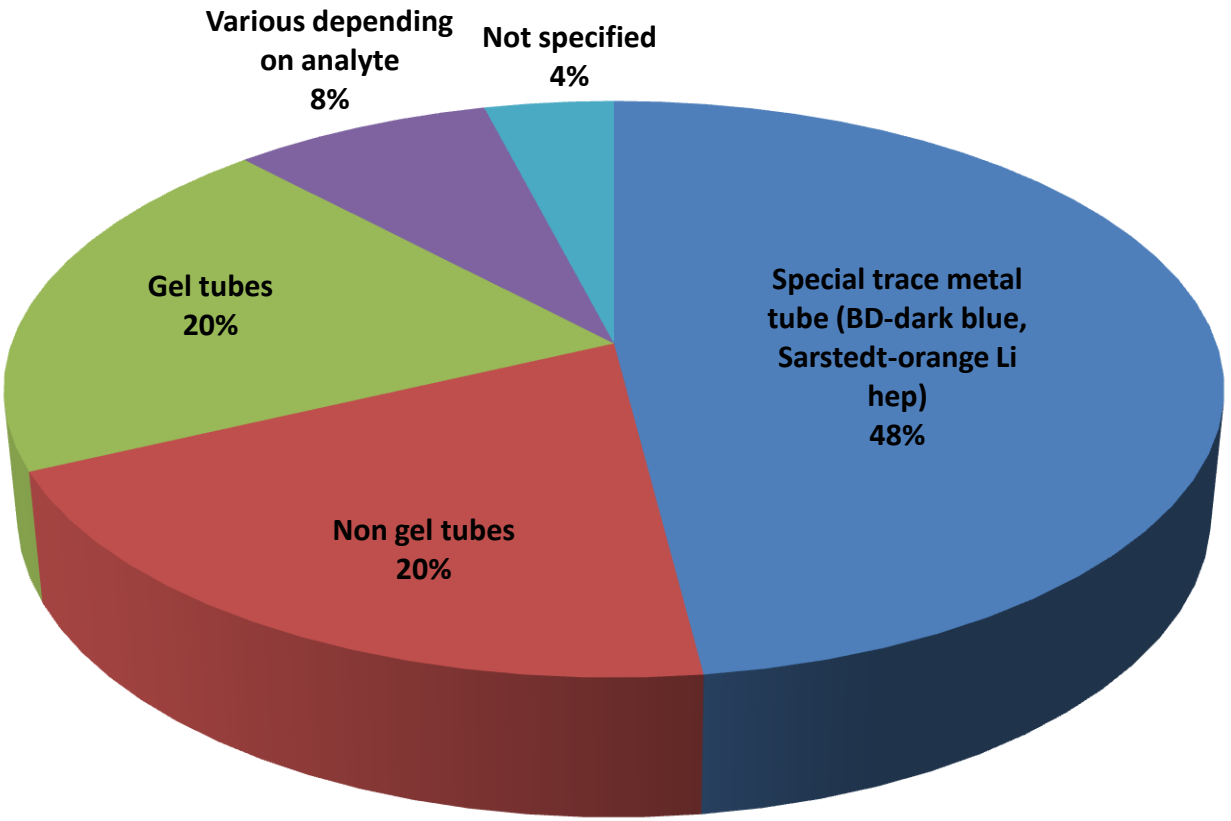
11 respondents use SST™/gel serum/plain clotted serum except for the following locations which use PST™/gel LiHep plasma/LiHep plasma



Q8

Blood tubes

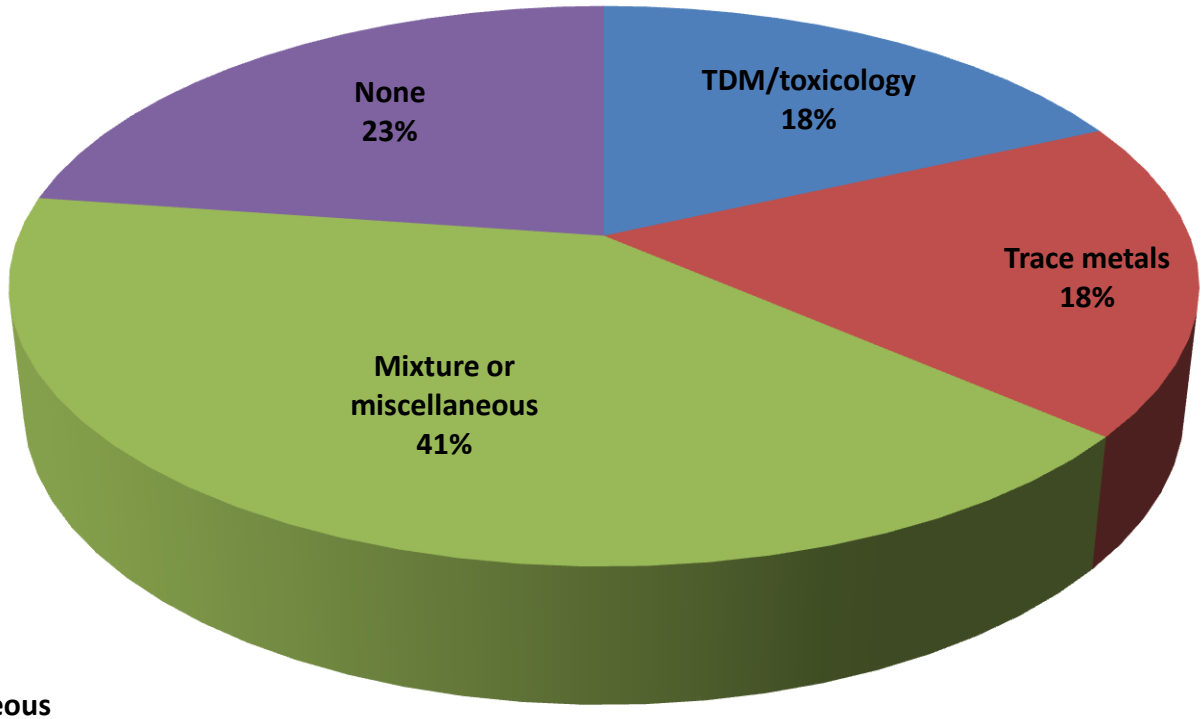
For trace element analysis, which specimen tubes does your laboratory accept?



Q9

Blood tubes

Please state any analytes/assays for which you avoid use of a gel-loaded tube?



"Currently evaluating evidence for therapeutic drug monitoring in gel-loaded tubes" Anon.

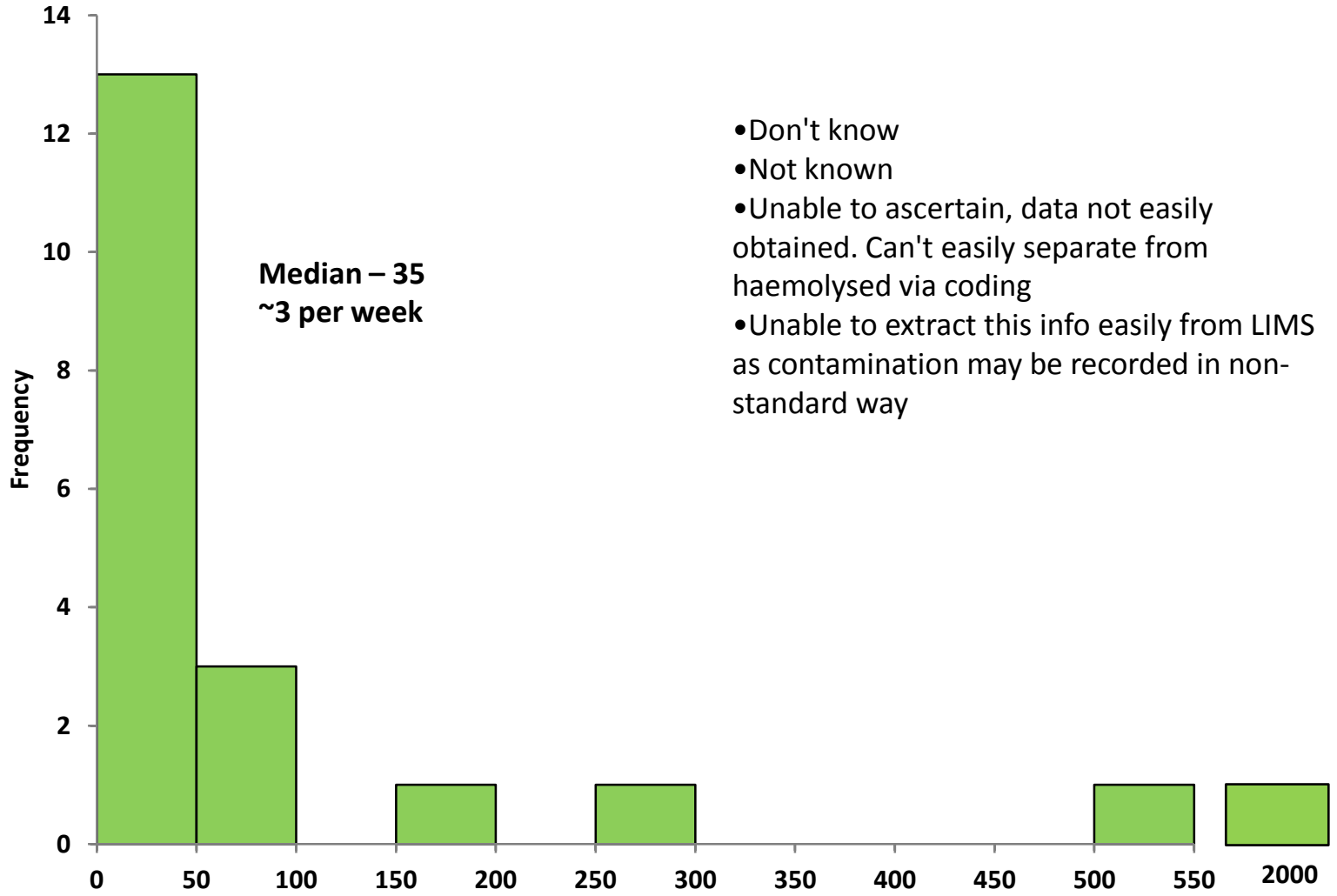
Mixture or miscellaneous

- COHb, MetHb, fleicainide, amiodarone, ethosuximide, lamotrigine, levetiracetam, Gal-1-PUT, Pb, Se, Mn, Hg, Al, Cu, Zn, Vits A, B1, B2, B6, C, E and K (X2)
- Amiodarone, anti-mullerian hormone, clozapine, copper, flecainide, hyaluronic acid, levetiracetam, prednisolone, procollagen peptide type 3, thyroglobulins, tobramycin and zinc.
- Trace elements and some drugs. No in house tests
- Too many to list individually – e.g. majority of metabolic tests, immunosupressants, HbA1c, Glucose, Trace Elements etc.
- Progesterone, P1NP and P3NP
- Autoimmunse serology (referred), allergy
- Hormones by mass spec - DHEA, Androstenedione, 17OHP
- AMH, 17OHP and any test requiring whole blood. Some drug assays as well however we do state that as long as assayed within 6 hrs we will accept gel tubes

Q10

Contamination - General

How many samples did you reject due to contamination in the last 3 months?



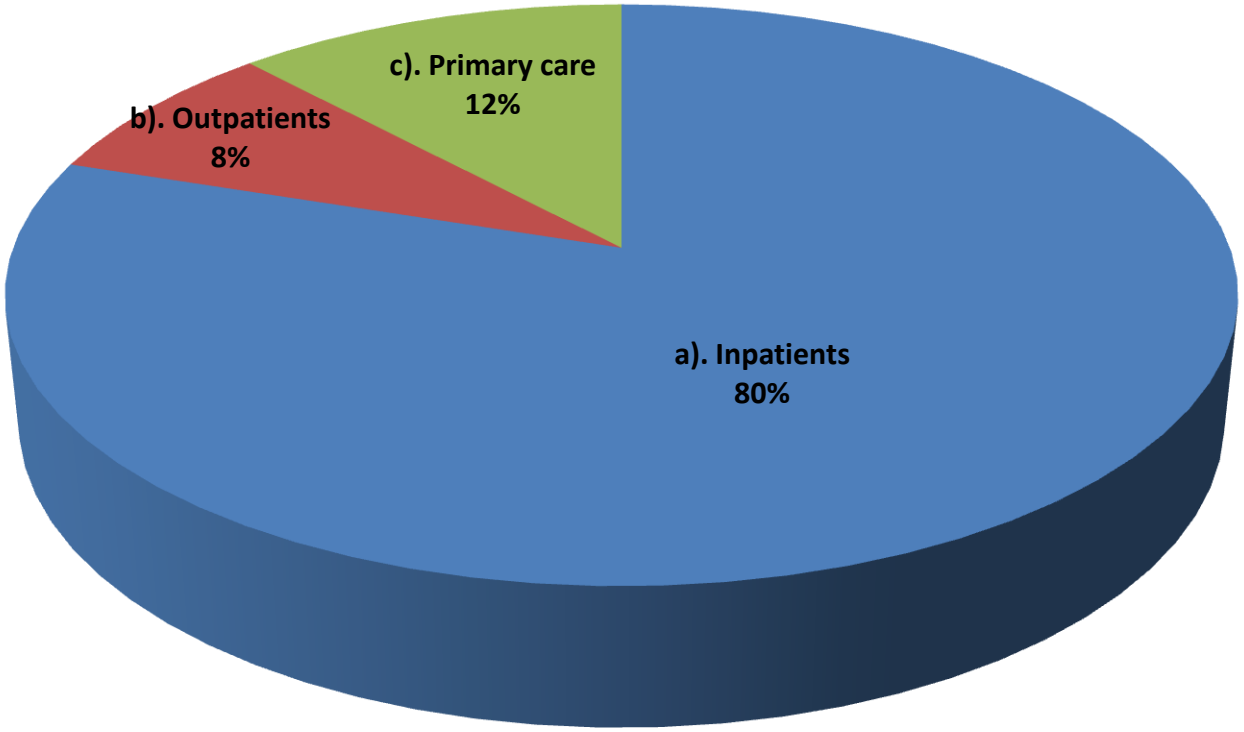
Median – 35
~3 per week

- Don't know
- Not known
- Unable to ascertain, data not easily obtained. Can't easily separate from haemolysed via coding
- Unable to extract this info easily from LIMS as contamination may be recorded in non-standard way

Q11

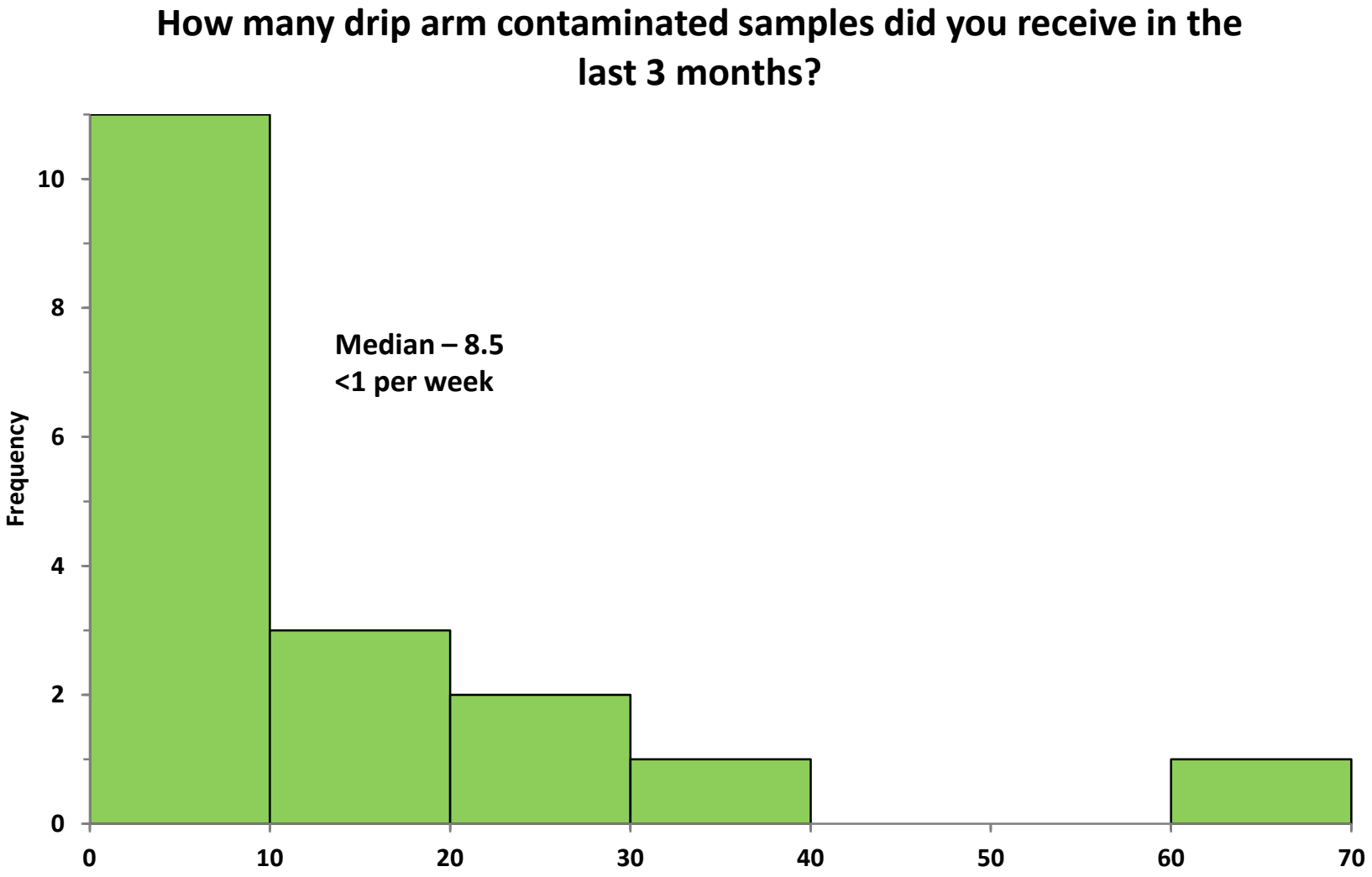
Contamination - General

Which location did most contaminated samples originate from?



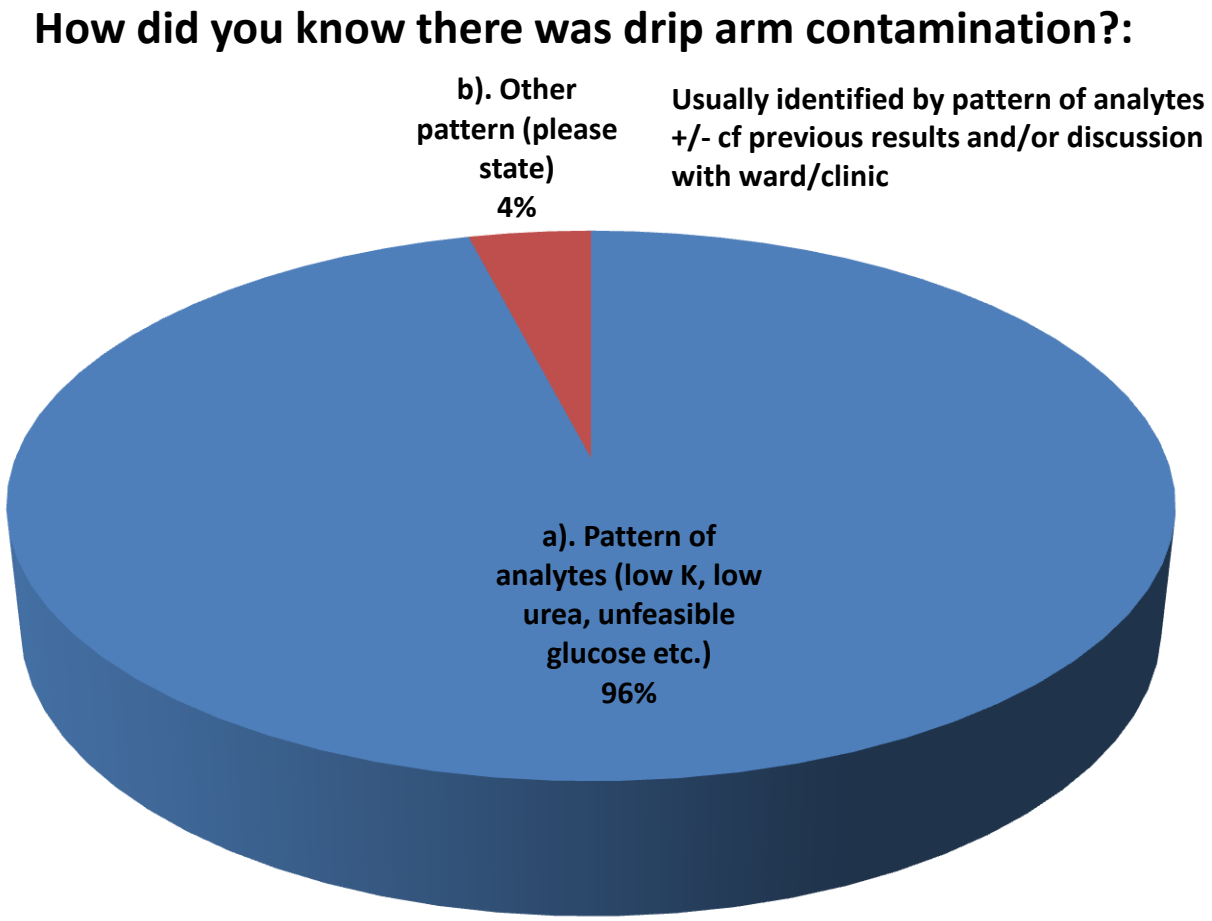
Q12

Contamination – Drip arm



Q13

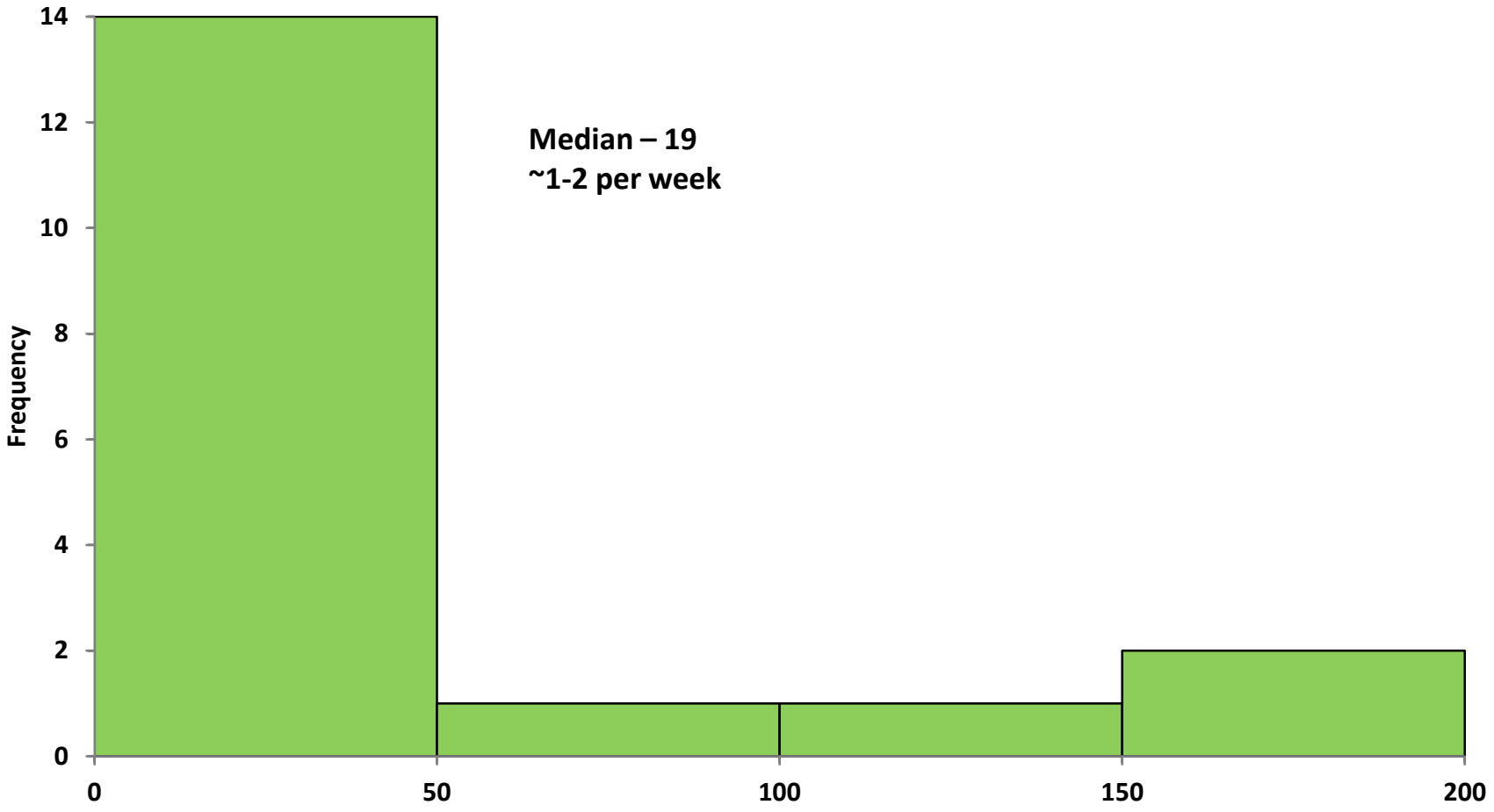
Contamination – Drip arm



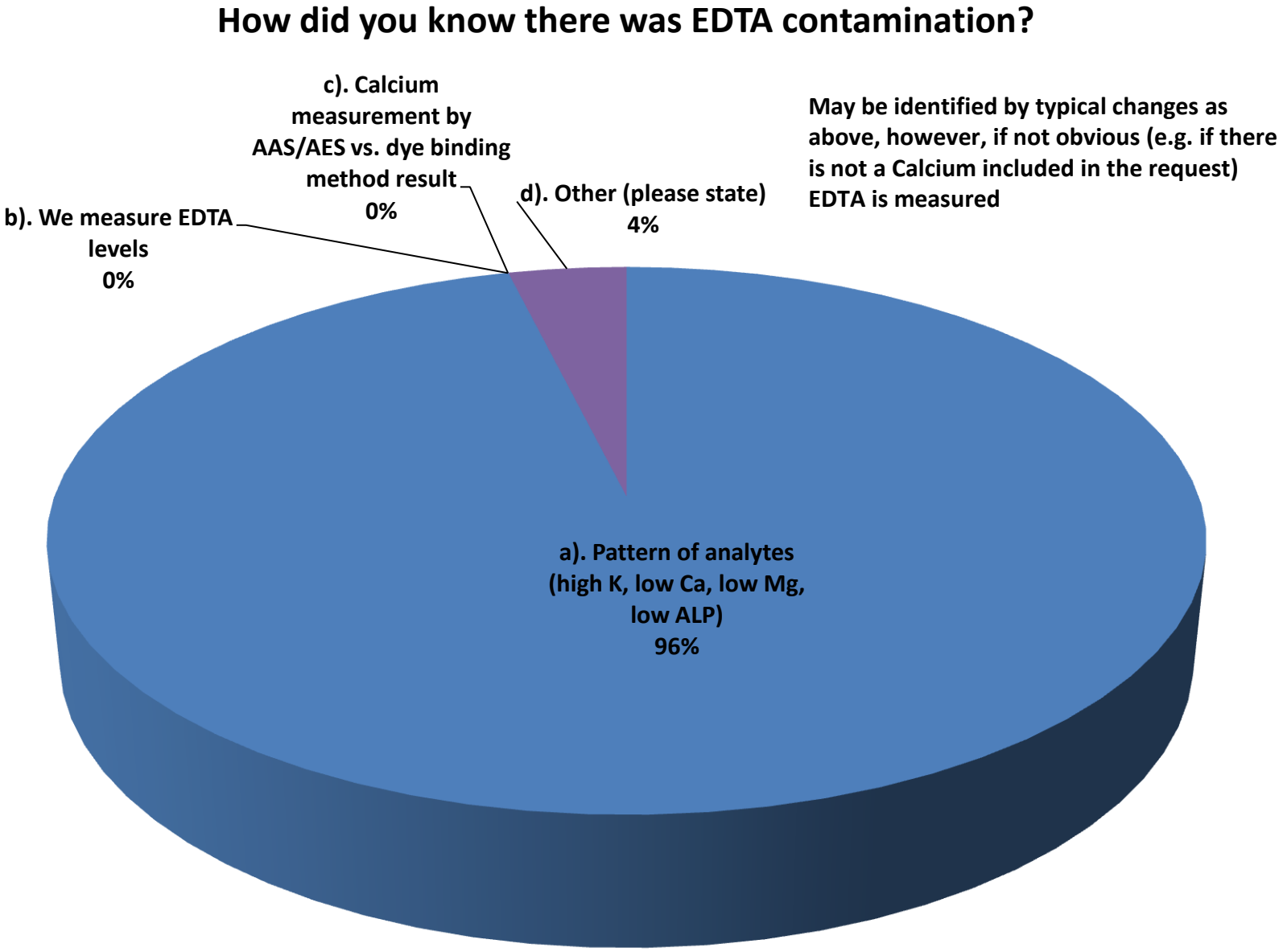
Q14

Contamination – EDTA

How many EDTA contaminated samples did you receive in the last 3 months?



Q15 Contamination – EDTA



Contamination – EDTA

Q16

If you have an EDTA assay, please describe the methodology.
This is a in house method run on the Cobas 8000. The assay is based on the following principle: At pH 4.8, EDTA abstracts copper ions from a violet coloured pyridylazonaphthol-copper complex (PAN-Cu) to yield yellow coloured free PAN. The decrease in absorbance is measured spectrophotometrically at 546 nm.

Q17

If your lab measures EDTA, which criteria do you apply for measuring it:
a). absolute thresholds (please state thresholds used below)
b). at BMS's discretion
c). at Duty Biochemist's discretion
d). other (please state)

A combination of the above methods. EDTA is automatically added based on absolute thresholds. However, BMS discretion is used to determine if the test is required i.e. it can be cancelled if the sample is clearly EDTA contaminated. Duty Biochemist (and BMS) may add EDTA to samples that do not meet thresholds but look suspicious

If absolute thresholds used, please state:
K = >6.0, AdjCa = <1.8

Q18

If you use an EDTA assay what is the cut-off for presence of significant amounts of EDTA?
>/=0.1 mmol/L

Q19

If you use an EDTA assay, is the cut-off the same for all analytes?
Yes

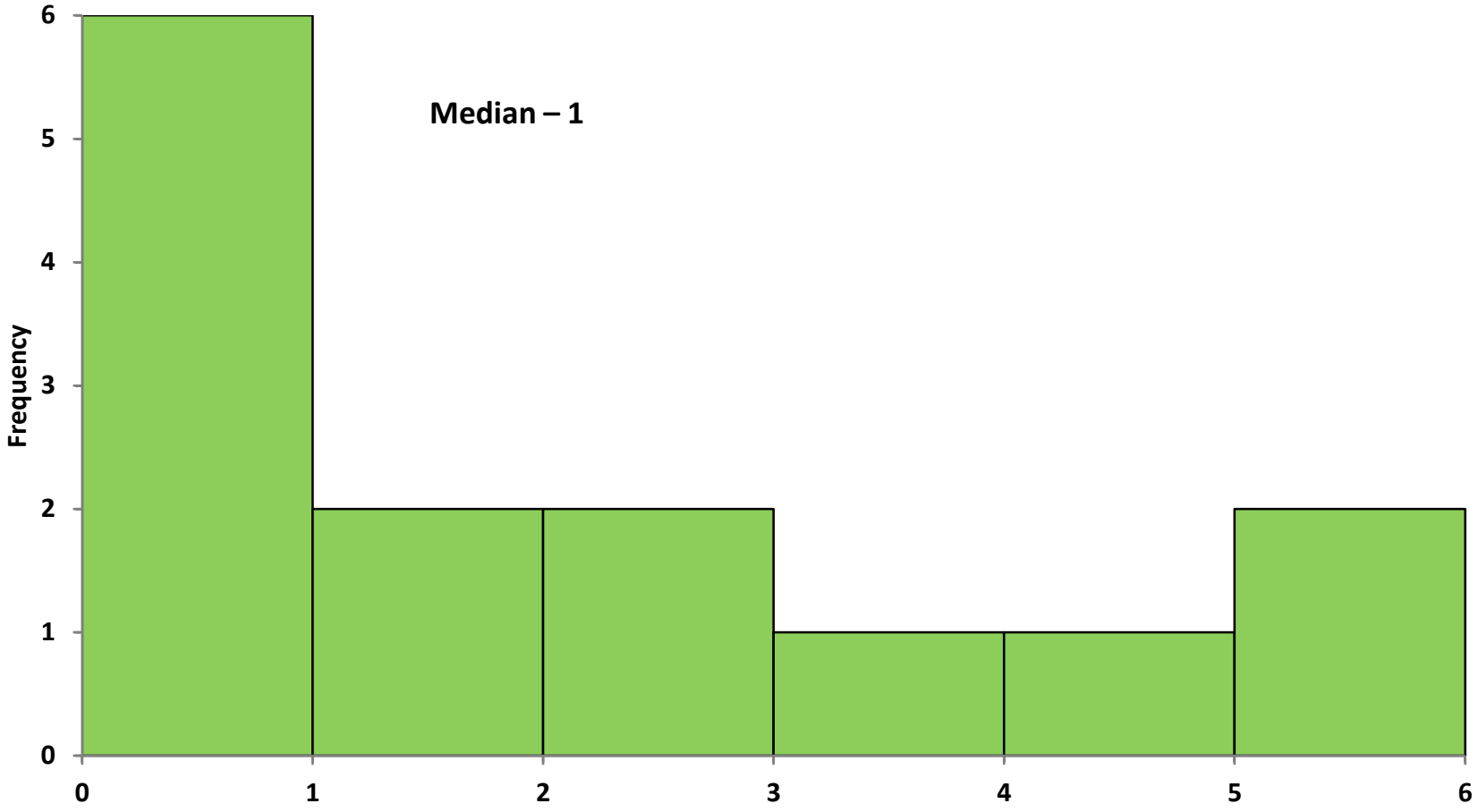
Q20

If you answered 'no' to Q19, please list the analytes and cut-offs here
Not applicable

Q21

Contamination – Citrate

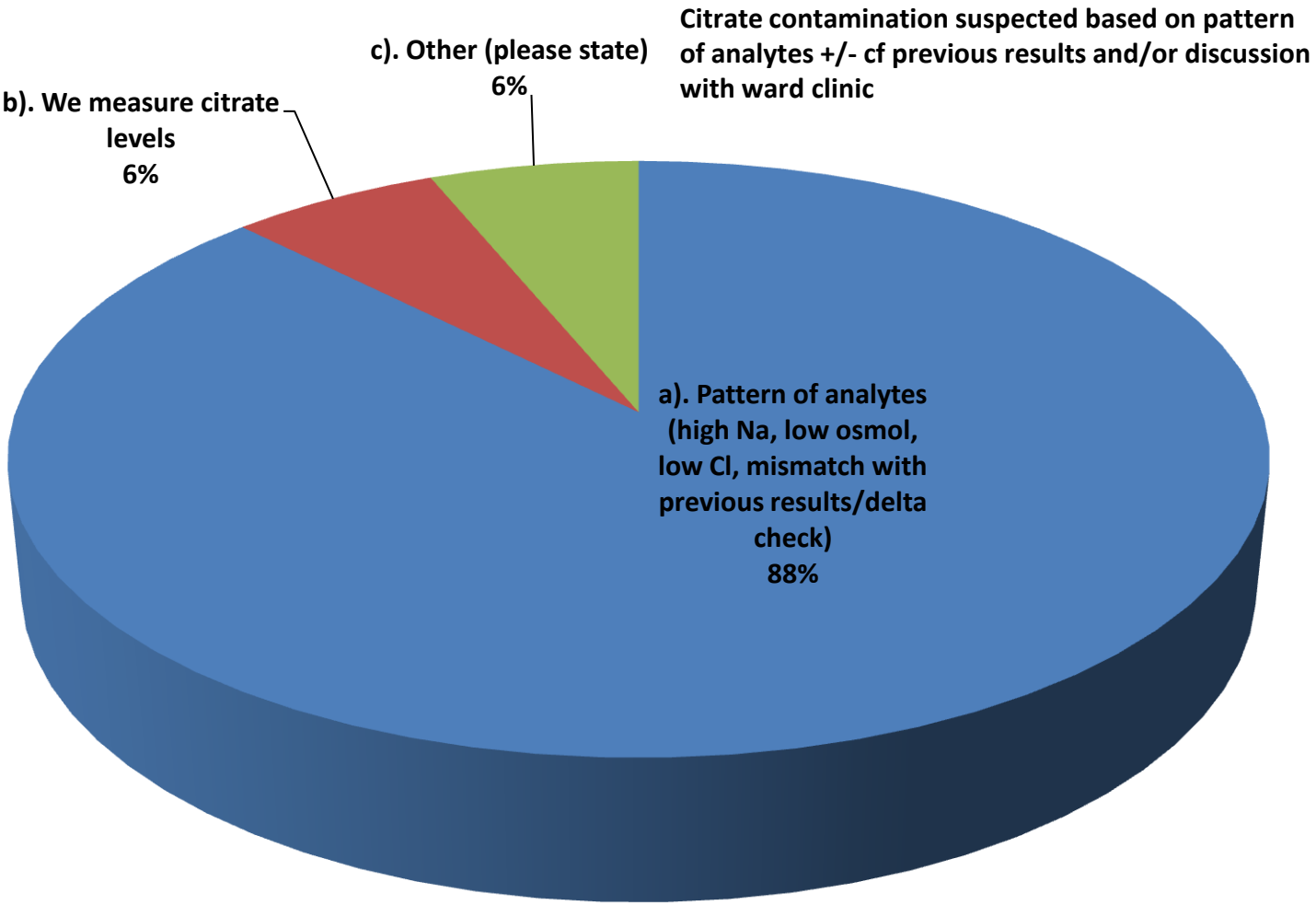
How many citrate contaminated samples did you receive in the last 3 months? (either citrate tubes, or Citra-Lock™)?



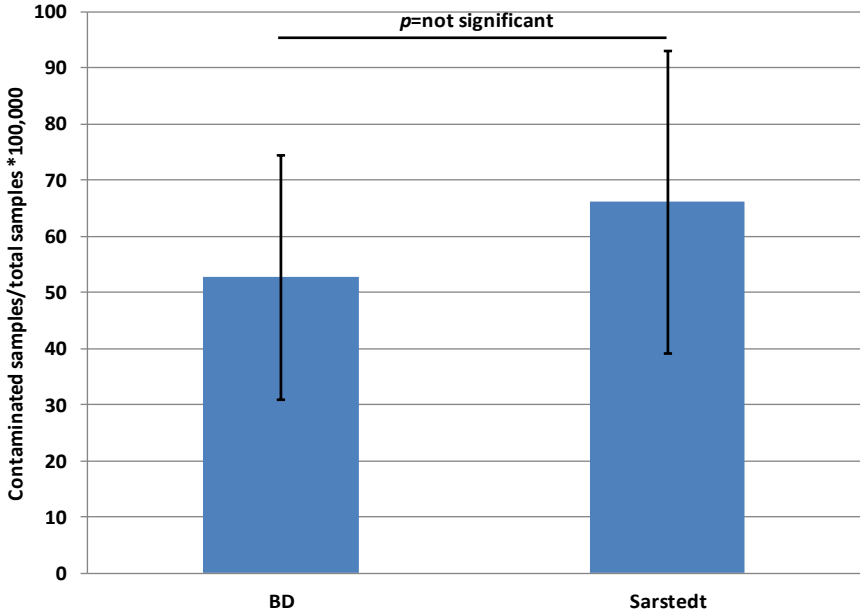
Q22

Contamination – Citrate

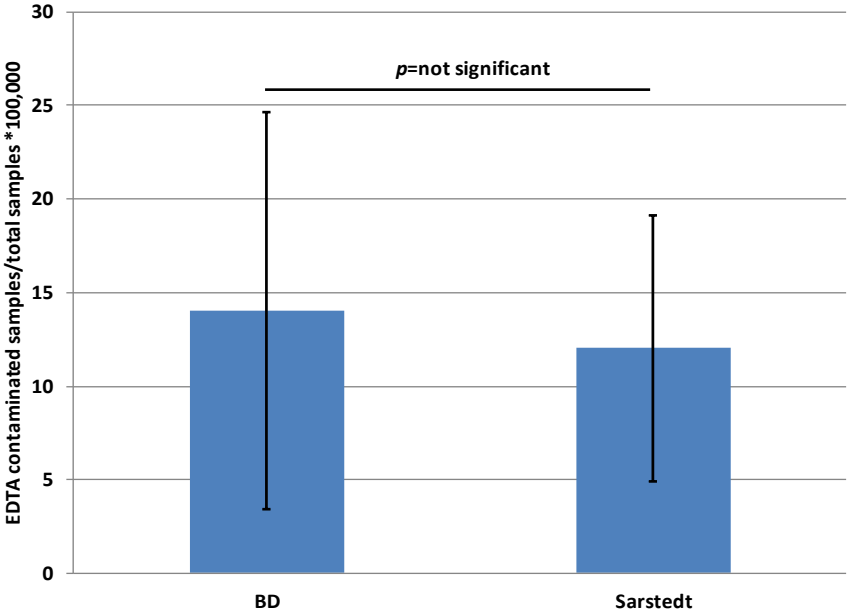
How did you know there was citrate contamination?



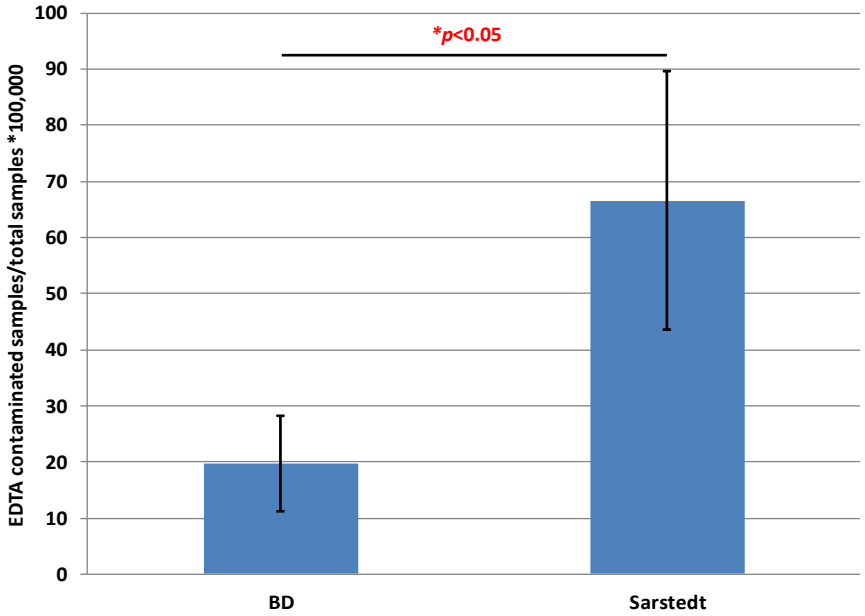
Total contamination rate by tube manufacturer



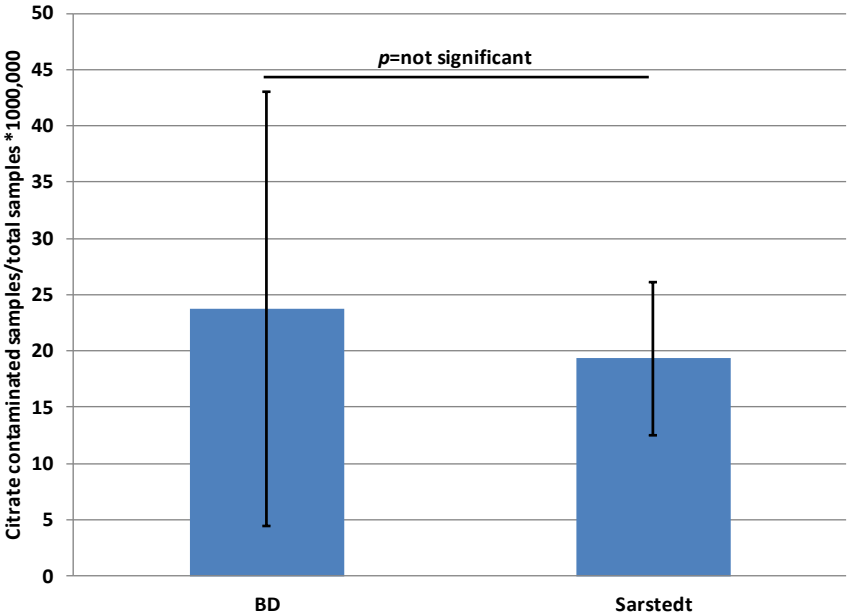
Drip arm contamination rate by tube manufacturer



EDTA contamination rate by tube manufacturer

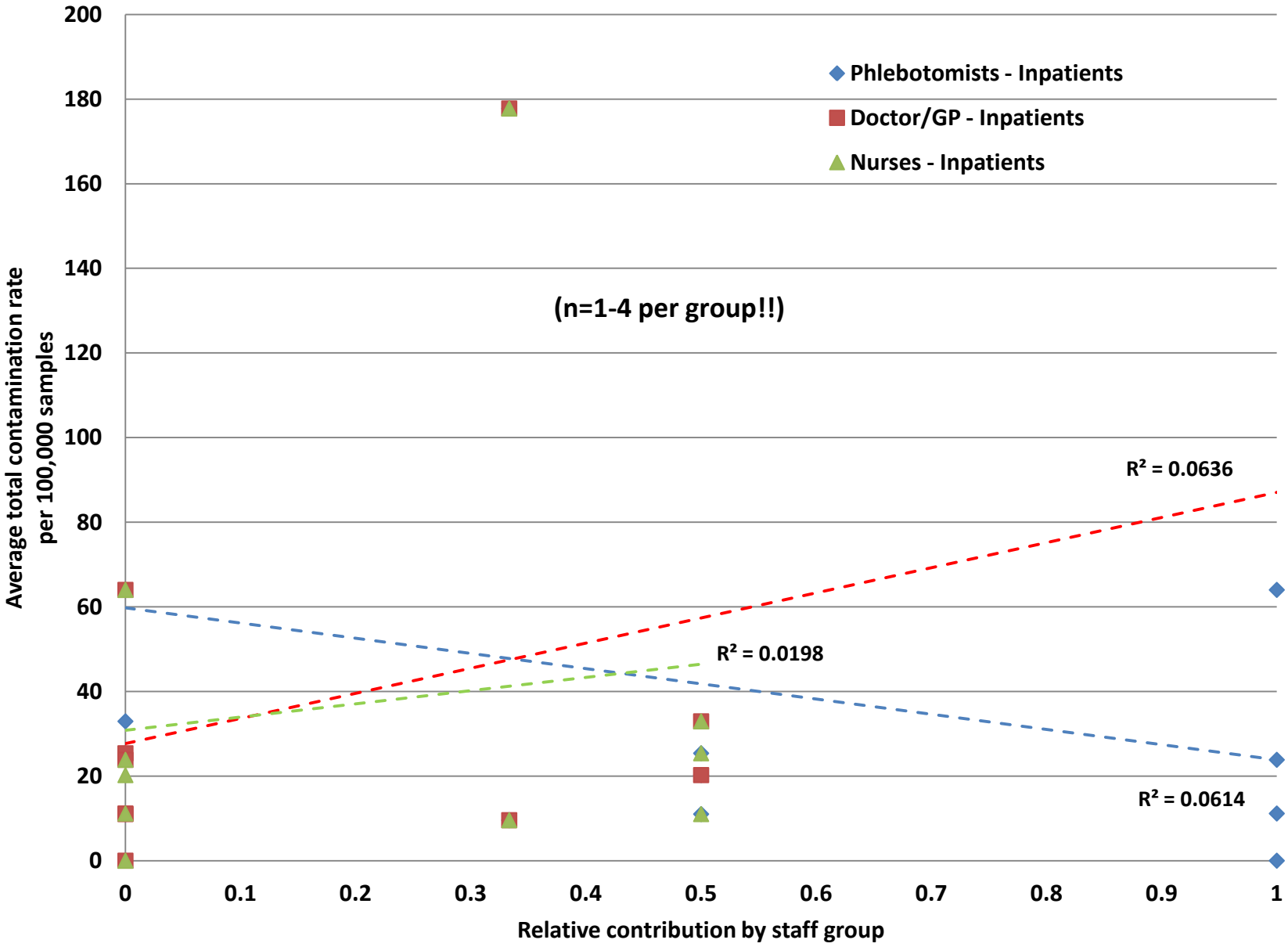


Citrate contamination rate by tube manufacturer



Venipuncture

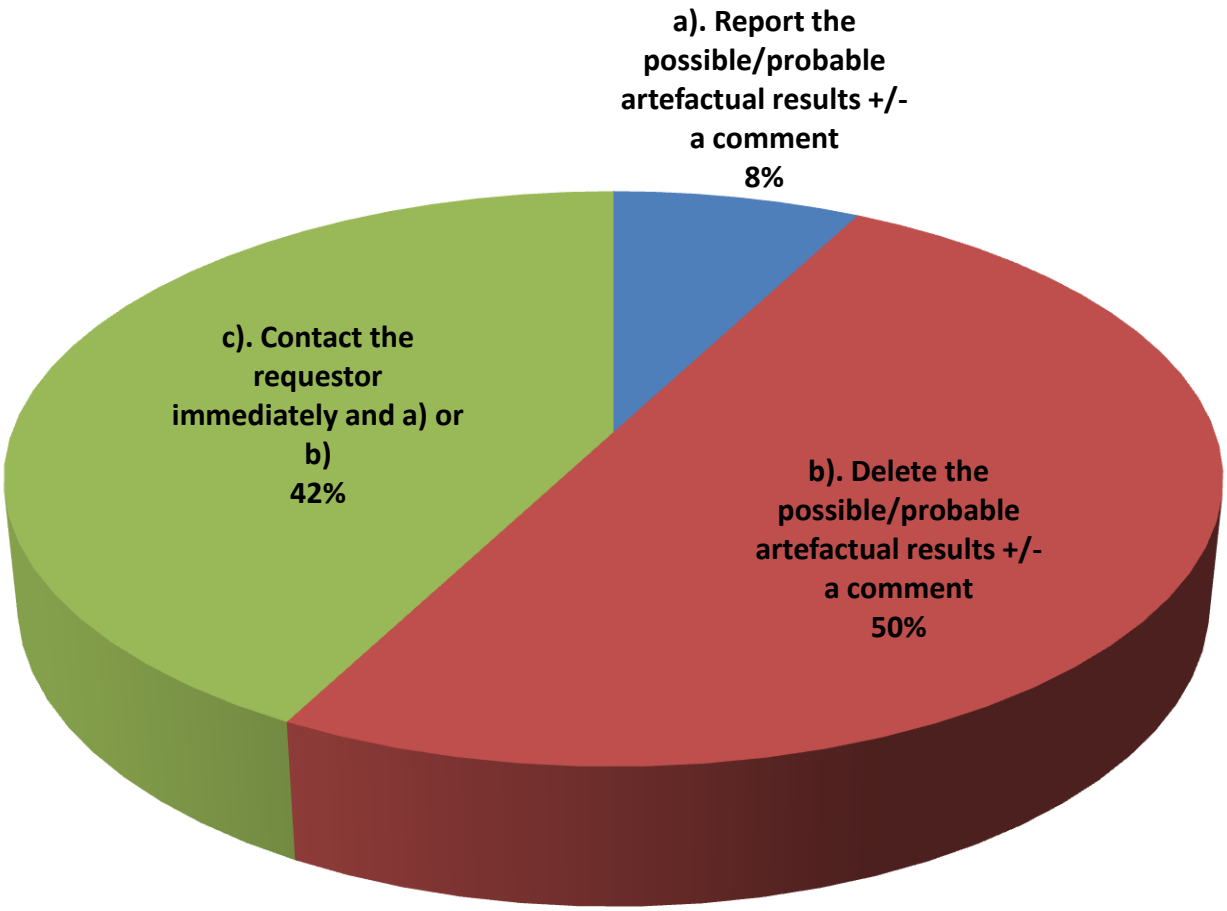
Contamination rates by staff group



Q23

Results reporting

What is your local procedure for reporting contaminated samples?

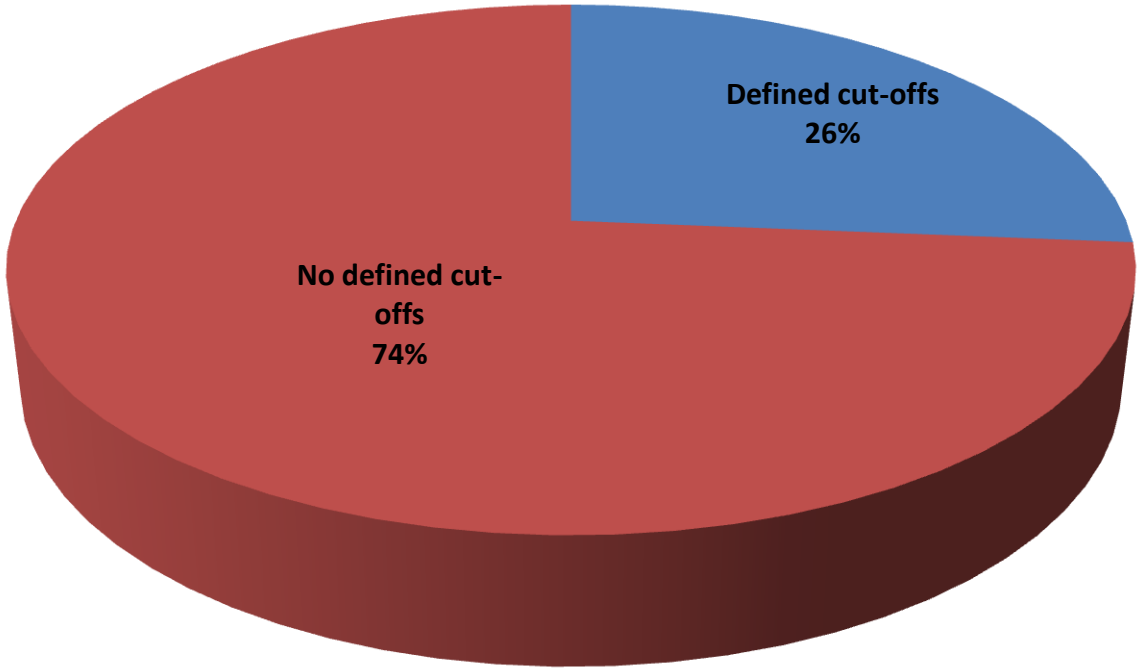


"Delete results *where obvious* (these can be picked out by our search), report with comment when *borderline* (data not extracted)"

Q24

Results reporting

If you don't have EDTA/citrate assays, and suspect contamination based on other results (e.g. K, Ca, Na), which cut-offs do you use for deleting results?



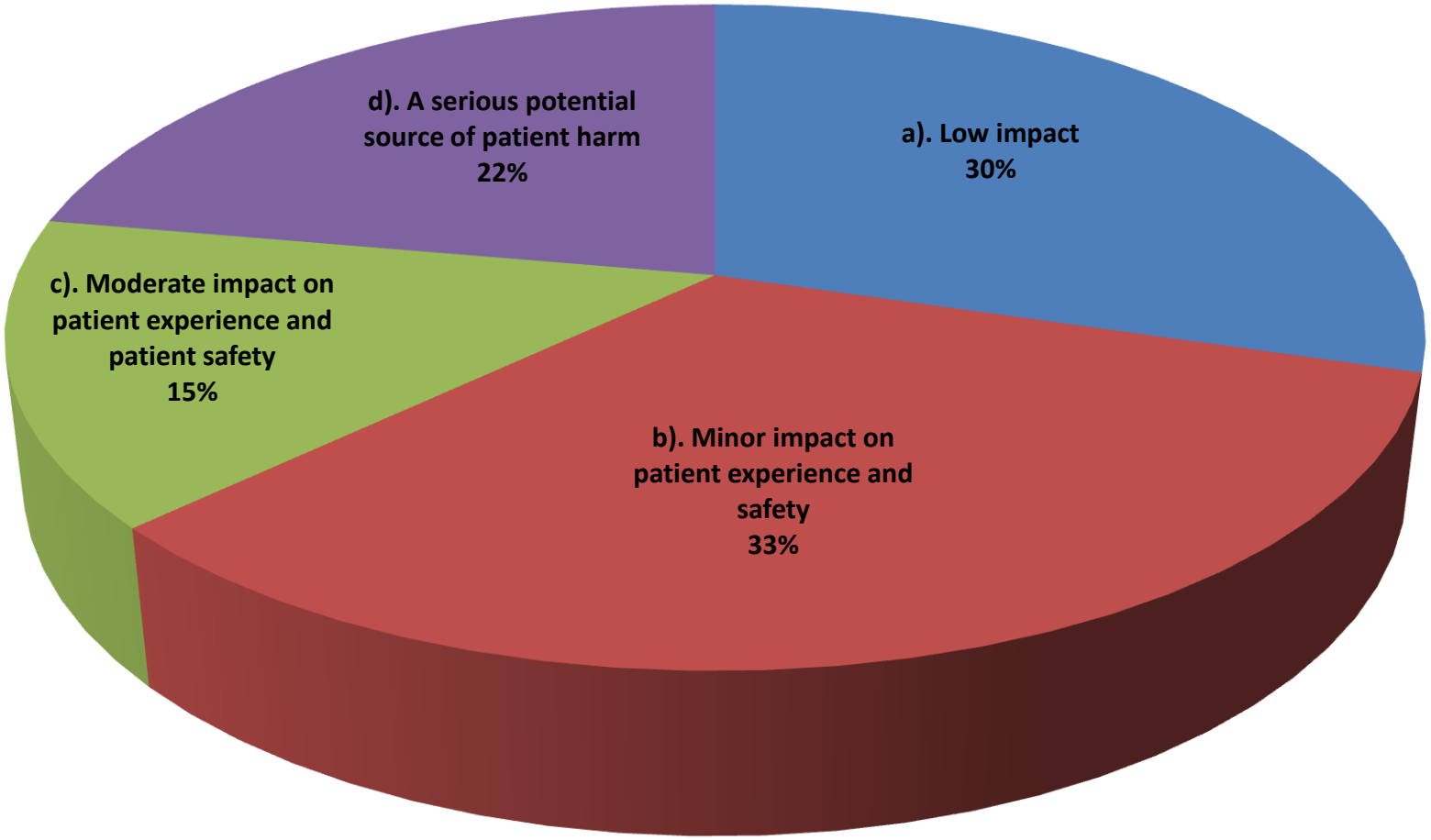
- K>10 mmol/L and/or Ca <0.5 mmol/L *n*=4
- Citrate - Na> 160 mmol/L or 20 mmol/L increase in Na plus Cl <108 mmol/L *n*=1

- Results appear to be incompatible with life
- Over top K and Very low Calcium, High Sodium but not corresponding Osmolality
- Combined picture, impossible to state cut-offs, delta check etc used
- Don't use a cut-off, Biomedical Scientist/Clinical Scientist decision
- Each case individual
- No cutoff - look at previous results, add calcium/ALP and review
- No set cut-offs, a decision is made by BMS staff based on the pattern of results observed.
- No specific cut offs just look for low K/Ca
- Not assigned cutoffs. Judgement used.
- Suspicion
- No defined cut-offs.
- No specific cutoffs used.
- Unsure
- If contamination is suspected all results are removed

Q25

Risk management

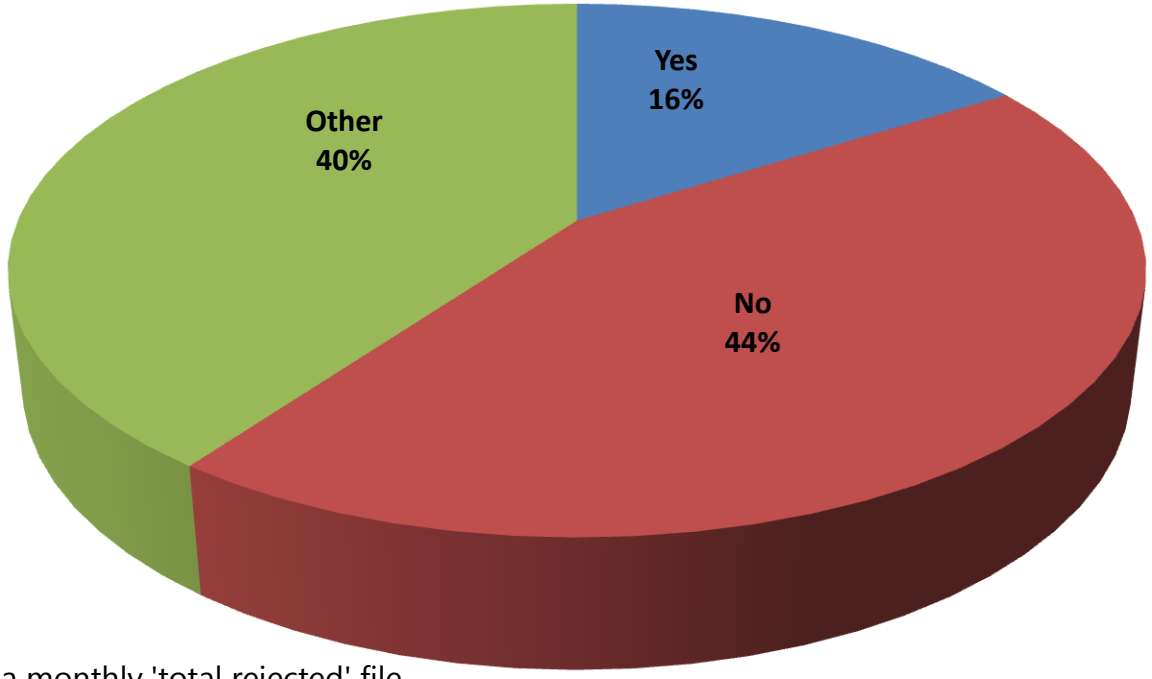
In your opinion, how would you grade the problem of sample contamination?



Q26

Risk management

Do you report suspected/confirmed contamination events in a patient risk management system (Datix)?



•Yes, though as a part of a monthly 'total rejected' file
•No but included in the in-house error tracking process.
•Not routinely unless an artefactual result wasn't detected by the lab and reported in error with potential for patient harm.
•Routinely no, however this would depend upon the individual situation/clinical scenario.
•Sometimes
•Usually trapped and comment put on report
•We only report a datix if the contamination was identified after the results were released.
•Depends. Most of the time our lab staff notice before results are reported and don't release the results, they just ask for another sample. In which case we wouldn't Datix it. If we had to amend results, we'd Datix it. But really it's the ward who ought to Datix it, which sometimes happens, in which case we wouldn't bother.
•If contaminated results have been missed
•If we reported a result on a sample which was later found to be contaminated we would record it in Datix or Q Pulse. If we spotted the problem and did not report a result we would get in touch with the requestor and leave it to them to record it in Datix.

Limitations

- Modest sample size + partial responses
- Limited time frame (3 months)
- Limited statistical power
- Under-reporting
- Study bias(es) e.g. recall bias

Key findings	Possible solutions
1) Recording and extracting contamination data from LIMS is a challenge for a large proportion of UK laboratories	•Work with LIMS providers, labs IT teams •Encourage use from senior management •UKAS, engage with local laboratory Quality/compliance teams
2) There is potentially a lack of awareness of correct 'order of draw' for venous blood collection among laboratory and clinical professionals	•Education and communication with phlebotomists/nurses/Drs 'Best practice' guidance from professional bodies (ACB/RCPath/IBMS)
3) A significant proportion of laboratories continue to accept gel-loaded tubes for trace element analysis; little consensus on which other tests to avoid use of these	•Engage with trace elements laboratories and tube manufacturers •'Best practice' guidance from professional bodies (ACB/RCPath/IBMS)
4) Contamination appears to be a particular problem for inpatients (EDTA>drip arm>citrate); a location where several staff groups contribute to blood collection	•Explore further the factors underlying higher rates among inpatients •Review practice
5) EDTA/citrate assay use is not widespread	•Recommend uptake? •Review published evidence/more studies

Key findings	Possible solutions
6) The majority of contamination is indentified by pattern of test results - ?a suboptimal method for detecting more subtle cases	•Local/National protocols including thresholds for spotting these
7) Certain tube manufacturers might be more prone to EDTA contamination than others (Sarstedt>BD)	•Investigate why •Work with manufacturers
8) There is no National consensus on if/how best to report contaminated samples	•'Best practice' guidance from professional bodies (ACB/RCPath/IBMS)
9) There is no National consensus on if/how these should be recorded in patient risk management systems and where the responsibility lies (laboratory vs. ward)	•'Best practice' guidance from professional bodies (ACB/RCPath/IBMS) •Better engagement with service users
10) There is a perception among a significant proportion of senior laboratory professionals that sample contamination has low or minor impact on patient safety	•Challenge the perception!

Acknowledgements

- Dr Chris Chaloner, ACB Scientific Committee
- National Clinical Biochemistry Audit Group
- ACB office esp. Mike Lester & Ashley Shalloe,
- Respondents

The Association for
Clinical Biochemistry
and Laboratory Medicine