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UK NEQAS for Blood Coagulation D-dimer Point of care testing programme: A review of data

DP Kitchen[1] , L Brown[1] , S Munroe-Peart[1] , I Jennings[1] , S Kitchen[1] , ID Walker[1]
UK NEQAS BC, Sheffield, UK

UK NEQAS Blood Coagulation

INTRODUCTION

Point of care (POC) D-dimer testing is frequently used to assess a patient with suspected VTE. When used with a clinical score and a cut off value for the POC D-dimer test users can decide whether to refer the patient for further testing such as a scan.

UK National External Quality Assessment Service for Blood Coagulation (NEQAS BC) has been providing External Quality Assurance (EQA) testing for POC D-dimer testing for users of Roche Cobas h232 and Quidel Triage devices since 2014. Currently registered for the programme are 106 h232 users and 39 Triage users

AIM

To provide EQA for the POC D-dimer testing and demonstrate the variability of these tests both for the result achieved and the interpretation of this result.

METHOD

Samples are lyophilised citrated plasma provided with a pre measured volume of diluent and a disposable pipette such that no laboratory equipment is needed. Method specific performance assessment is undertaken. Median values are calculated and the furthest from the median (up to 10% highest and up to 10% lowest) are considered “outwith consensus”. A patient scenario is also provided and users are required to choose either “no further investigation required” or “further investigation required” based on their local test result and the pre test probability score provided. Post analytical interpretation is scored as “within consensus” if it is in agreement with 80% or more of all users interpretations.
If a centre is outwith consensus in 3 consecutive surveys for either their result or interpretation they will be classified as “persistently outwith consensus” and receive contact from the UK NEQAS BC programme Director.

RESULTS

- Results are shown for the last 8 surveys. Table 1 shows results from the h232 users and table 2 shows results from the Triage users.
- The sample distributed in May 2019 had a very low level D-dimer. The majority of h232 users gave results of 0.1 or <0.1µg/ml FEU which resulted in a high %CV as one centre reported a result of 0.34µg/mg FEU. Triage users all reported results of 100 or <100ng/ml FEU for this sample.
- Coefficients of Variance (CV) for h232 users ranged from 15.6 -31.5% with an average of 21.1%
- CVs for Triage users ranged from 13.2-27.4% with an average of 20.3%

Table 1

Survey	Cobas h232 median µg/ml FEU	CV%	% Outwith Consensus results	Cobas h232 interpretations	% Outwith Consensus interpretation
Feb 2018	0.25	20.1	19.6	89.9% No further investigations	10.2
May 2018	0.25	17.3	14.5	100% No further investigations	0
Sept 2018	0.23	17.1	9.3	not scored 80% majority not reached	not scored
Dec 2018	1.52	23.4	16.7	98% Further investigations	2
Feb 2019	0.36	15.6	14	92% No further investigations	8
May 2019	0.1	31.5	1.9	89.4% No further investigations	10.6
Sept 2019	0.37	24.1	17	91.5% No further investigations	8.5
Dec2019	0.995	19.7	18.3	98% Further investigations	2

Table 2

Survey	Triage median ng/ml FEU	CV%	% Outwith Consensus results	Triage interpretations	% Outwith Consensus interpretation
Feb 2018	296	17.4	8.7	89.5% No further investigations	10.5
May 2018	443	13.2	14.7	not scored 80% majority not reached	not scored
Sept 2018	402	23.4	16.1	not scored 80% majority not reached	not scored
Dec 2018	1810	25.2	18.9	100% Further investigations	0
Feb 2019	597	18.1	15.1	88.9% Further investigations	2
May 2019	100	0	0	93.3 No further investigations	6.7
Sept 2019	357	27.4	15.2	not scored 80% majority not reached	not scored
Dec2019	1400	17.5	17.1	100% Further investigations	0

- A small number of centres gave interpretations that were inappropriate based on their results.
- One centre had a result of 0.74ug/ml FEU and stated “no further investigation”, manufacturers stated cut off for this device is 0.5ug/ml FEU.
- For samples that were provided with a patient scenario of a Wells score of 3 or 4 a small number of centres stated “no further investigation required” ie they had results of below the cut off but did not take into account the Wells score provided (which should had led to further investigation).
- Some centres used a locally derived cut off rather than the manufacturers’ and had lowered the cut off “to ensure we don’t miss any VTEs.” One centre had lowered cut off from 0.5 to 0.3 µg/ml FEU.

CONCLUSIONS

- **EQA is essential for D-dimer testing whether in the laboratory or in a POC setting to ensure the quality of results.**
- **The interpretations of these results overall was good but some centres did not take into account the patient scenario and pre test probability score provided.**
- **We have also seen results which are over the manufacturers’ stated cut off which have been deemed by the user to not require further investigation.**
- **Not all centres use the provided manufacturers’ cut off value.**

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CONTACT INFORMATION

Lead author dianne.kitchen@nhs.net
General email address neqas@coageqa.org.uk.