UK NEQAS
Blood Coagulation

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**HIT EXERCISE July 2023:**

**DISTRIBUTED July 2023 Individual report v1.0**

This exercise comprised 2 samples for HIT assays, **HIT 23:03** was from a normal patient without confirmed HIT using the Werfen Acustar CLIA assay and **HIT 23:04** from a HIT positive donor by Acustar assay that was titrated to 3U/ml using normal plasma.

**Commentary:** Samples were sent to 72 centres that had registered for this programme, and results were returned from a total of 68 centres. The following pages show the overall results for each of the HIT assays, together with a summary of method-specific medians where possible.
Table 1 Summary of quantitative and qualitative results.

| Method | HIT23:03 n | HIT23:03 Median (OD unless stated) | HIT23:03 Interpretation Pos/Neg | HIT23:04 n | HIT23:04 Median (OD unless stated) | HIT23:04 Interpretation Pos/Neg |
|---|---|---|---|---|---|---|
| Lifecodes ELISA IgG | 8 | 0.12 | 0/8 | 8 | 1.56 | 8/0 |
| Lifecodes ELISA GAM | 2 | 0.21 | 0/2 | 2 | 2.02 | 2/0 |
| Stago Asserachrom HPIA IgG | 4 | 0.04 | 0/4 | 4 | 1.90 | 4/0 |
| Stago Asserachrom HPIA GAM | 1 | 5.2% | 0/1 | 1 | 90.5% | 1/0 |
| HIPA functional assay | 1 | | 0/1 | 1 | | 1/0 |
| Werfen Acustar CLIA IgG | 29 | 0.02 | 0/29 | 29 | 3.03 | 29/0 |
| Werfen LIA IgGAM | 14 | 0.2 | 0/14 | 14 | 2.35 | 14/0 |
| Stago STIC/Biotec Mil IgG | 17 | | 0/17 | 17 | | 17/0 |
| Overall interpretation | | | 0/76 | | | 76/0 |

We have calculated % deviation and z-scores by peer group where participant numbers ≥10 and assessed performance against overall interpretation.

Report authorised by C Reilly-Stitt, Deputy Manager 12/9/2023 .

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## ELISA and Non ELISA Assays

Table 2 shows the median results by method for sample HIT 23:03.
2 different suppliers of ELISA kits were employed for detection of HIT of which no single kit was used by >10 centres. Three different Non ELISA methods were used by participants returning results for HIT 23:03. One set of data for a functional assay was returned for HIT 23:03.

Table 2. Assays results for HIT 23:03.

| | n | Median (OD unless stated) | CV (%) | Range (OD unless stated) | Interpretation Pos/Neg |
|---|---|---|---|---|---|
| Lifecodes ELISA IgG | 8 | 0.12 | - | 0.043-0.16 | 0/8 |
| Lifecodes ELISA GAM | 2 | 0.2085 | - | 0.208-0.209 | 0/2 |
| Stago Asserachrom HPIA IgG | 4 | 0.04 | - | 0.022-0.079 | 0/4 |
| Stago Asserachrom HPIA GAM | 1 | 5.2% | - | 5.2% | 0/1 |
| HIPA functional assay | 1 | - | - | - | 0/1 |
| Werfen Acustar CLIA IgG | 28 | 0.02* | 117.9 | 0-0.14 | 0/29 |
| Werfen LIA IgGAM | 14 | 0.2 | 54.7 | 0-0.3 | 0/14 |
| Stago STIC/Biotec Mil IgG | 17 | - | - | - | 0/17 |
| Interpretation | Positive 0/76 | | | | |
| Interpretation | Negative 76/76 | | | | |

Table 3 shows the median results by method for sample HIT 23:04.
2 different suppliers of ELISA kits were employed for detection of HIT of which one kit was used by >10 centres. Three different Non ELISA methods were used by participants returning results for HIT 23:04. One set of data for a functional assay was returned for HIT 23:04.

Table 3

| | n | Median (OD unless stated) | CV (%) | Range (OD unless stated) | Interpretation Pos/Neg |
|---|---|---|---|---|---|
| Lifecodes ELISA IgG | 8 | 1.558 | - | 1.21-2.177 | 8/0 |
| Lifecodes ELISA GAM | 2 | 2.024 | - | 1.25-2.798 | 2/0 |
| Stago Asserachrom HPIA IgG | 4 | 1.895 | - | 1.845-2.168 | 4/0 |
| Stago Asserachrom HPIA GAM | 1 | 90.5% | - | 90.5% | 1/0 |
| HIPA functional assay | 1 | - | - | - | 1/0 |
| Werfen Acustar CLIA IgG | 29 | 3.03 | | 2.15-5.46 | 29/0 |
| Werfen LIA IgGAM | 14 | 2.345 | | 1.9-2.92 | 14/0 |
| Stago STIC/ Biotec Mil IgG | 17 | - | - | - | 17/0 |
| Interpretation | Positive 76/76 | | | | |
| Interpretation | Negative 0/76 | | | | |

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We have calculated the UoM for both Werfen quantitative assays and they are tabulated below, table 4.

Table 4

| Assay type | Sample number | UoM |
|---|---|---|
| Werfen Acustar CLIA | 23:03 | 0.008 |
| Werfen LIA | 23:03 | 0.037 |
| Werfen Acustar CLIA | 23:04 | 0.146 |
| Werfen LIA | 23:04 | 0.093 |

**Performance scoring for HIT assays.**

The following performance methods have been applied to results in this exercise.

***Z scores:***

Participant performance is determined by z scores, calculated as follows. The central reference point is taken as the peer group mean. The robust mean and SD are calculated by statistical exclusion of outlying results. The z-score is calculated as

***[result – peer group mean] / SD.***

A z-score of >+/-2 is considered out with consensus, with a warning flag; a z-score of >+/-3 is considered out with consensus with an action required flag. 'Action required' is also applied to two consecutive z scores >+/-2. Two consecutive surveys with z scores >+/-3, or 3 surveys with z scores >+/-2 will be considered persistently out with consensus.

The terminology "action" and "warning" is derived from ISO13528 guidance on use of z scores in proficiency testing programmes. We suggest that an "action required" flag would prompt a laboratory to review their assay results and decide whether further action is warranted; in particular, the clinical implication of their performance should be considered. A "warning" flag indicates a result outlying from the median, which should be monitored in future surveys.

**% Deviation from the median**

The central reference point is taken as the peer group median. Individual results are calculated as a percentage of this median.

***Sharing results:*** *UK NEQAS (Blood Coagulation) survey reports are posted to the secure online data entry system, accessible only by participant number and unique password. UK NEQAS (Blood Coagulation) does not share participant information with any 3rd party, except with respect to unresolved performance issues, please see our privacy policy, available online at www.neqascoag.org. However, as articulated in the Pathology Quality Assurance Review, participants are encouraged to share their EQA performance data both within and outside of their department.*

*Samples in this exercise passed homogeneity criteria consistent with ISO15328 standards. All samples also undergo stability testing for the duration of each survey. Homogeneity and stability tests are subcontracted to the STH NHS Trust coagulation department.*

*HIT surveys are not within the scope of accreditation but we do plan to apply for full accreditation before our next assessment, in 2023*

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