Developing EQA: Glandular Fever Screening
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Introduction

UK NEQAS Haematology supplies a comprehensive range of external quality assessment (EQA) programmes designed to support the quality assurance needs of participating laboratories. Glandular Fever screening kits are widely used in blood sciences laboratories, both in routine and out-of-hours services. Recent feedback from participants demonstrated the development of Glandular fever screening EQA was identified by participants and the highest priority to be supplied as part of our standard services.

Background

The kits screen for the presence of heterophile antibodies (representative of Epstein-Barr virus infection) that are strongly connected with a clinical picture of Glandular Fever. The speed and simplicity of use of the kits mean that they form an essential part of the laboratory’s first line of testing for the infection. The development of a new EQA programme occurs in stages: pre-pilot testing to demonstrate that the material is fit-for-purpose, pilot exercises to test the programme design with a range of laboratories, followed by the launch of a full programme accredited to ISO17043.

Initial Developments

**Pre-Pilot Testing**

- **6 Donors**
  - Kit A
  - Kit B
  - Kit C
  - All in consensus

Six donor plasmas positive for EBV heterophile antibodies were tested in-house and by five UK NEQAS participating laboratories, by three of the most commonly available screening kits (Fig. 1). Initial studies were also undertaken to assess the compatibility of the kits with donor plasma after the addition of antibiotics and anti-fungal agents. Temperature stability was tested by maintaining specimens for one week at temperatures up to 37°C, to represent the extremes of conditions that might be experienced in transit. These initial studies confirmed that the selected survey material was sufficiently robust to progress to the next, pilot stage.

**1801GF Pilot**

Two negative and one positive specimens were sent to 30 volunteer UK NEQAS participating laboratories in the first pilot exercise. Laboratories were selected on the basis of the Glandular Fever Kit in use, to ensure a representative range of kits were assessed. Temperature stability testing was repeated (see Fig. 3) and the typical results obtained with different kits.

**Pilot programme opened to UK laboratories**

200 UK laboratories enrolled for the pilot programme in April 2019 and the first full pilot distribution was made in July 2019. The programme was renamed Infectious Mononucleosis Screening (MN).

Results

![Table](image)

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<th>1801GF1</th>
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![Figure 2](image)

Figure 2 – Summary results for 1801GF pilot survey

Participants in the first 1801GF pilot exercise were asked to report results as positive, weak positive or negative to simplify data collection. 29/30 (97%) of laboratories returned results for the pilot exercise. There was just one out-of-consensus result with a negative sample reported as positive; this was due to a transposition error of either the specimen or the results at data entry.

![Figure 3](image)

Figure 3 – Results for Temperature stability testing

![Figure 4](image)

Figure 4 – Typical results obtained with the UK NEQAS survey material

Conclusions

We are confident that the survey material and operation of the programme is sufficiently robust to allow the assessment of laboratory performance. The programme will be offered on a pilot basis during 2019 to allow us to gather sufficient data for the development of performance assessment criteria.

Future Developments

- Programme is now open internationally to all interested participants.
- 200 participants registered for the pilot at July 2019.
- Frequency of distributions to be established with participants.
- Cumulative performance scoring is in development.
- Inclusion in our scope of accreditation is planned for 2020 (ISO 17043).