

INTRODUCTION

During the course of routine participation in PT, most laboratories will, from time to time, receive an unsatisfactory performance score for a particular analyte in a particular matrix. In the event that an unsatisfactory performance score is obtained in a PT, the laboratory should (and, if accredited, is required to) investigate the unsatisfactory performance in order to determine the root cause of the failure and the extent to which problems exist, or could potentially occur.

A number of previous studies have investigated the reasons for poor performance in PT schemes; this work from LGC brings together participant data from an 'up-to-date' survey amongst its large global participant base. Survey participants provided information on their PT participation, root cause analysis for unsatisfactory performance and the actions taken following each incident of unsatisfactory performance.

SURVEY STRUCTURE

The survey was made available to Proficiency Testing participants during the first quarter of 2023, by email and on social media. A total of 361 responses were received prior to the closure date.

Participants were asked to state the region/continent in which they were based. The survey was global in nature – although the largest number of responses were from PT participants based in Europe (>66% of all laboratories), a significant number of the respondents were based in Asia and North America (13.5% and 11% respectively), and all continents were represented.

The laboratories surveyed were asked to provide an indication of the number of PT tests undertaken and the number of different PT providers that they worked with over the last three years.

The majority of laboratories tested fewer than 20 PT samples in the 3 year period covered by the survey. However, a significant number of laboratories, more than 35, tested greater than 60 PT samples in the same time period.

In general, the number of different PT providers used by the participants was low with 66% of laboratories reporting that 3 or fewer different PT providers were used in the 3 years of the survey.

In total, the response to the survey indicated that 360 labs tested 13435 PT samples over the three years of the survey.

The laboratories were asked to indicate how many instances of poor performance had occurred during the last 3 years of their PT participation. In total 993 cases of poor performance were reported. For all of the participants who reported data, the median rate of PT poor performance over the three years surveyed was 5.6%

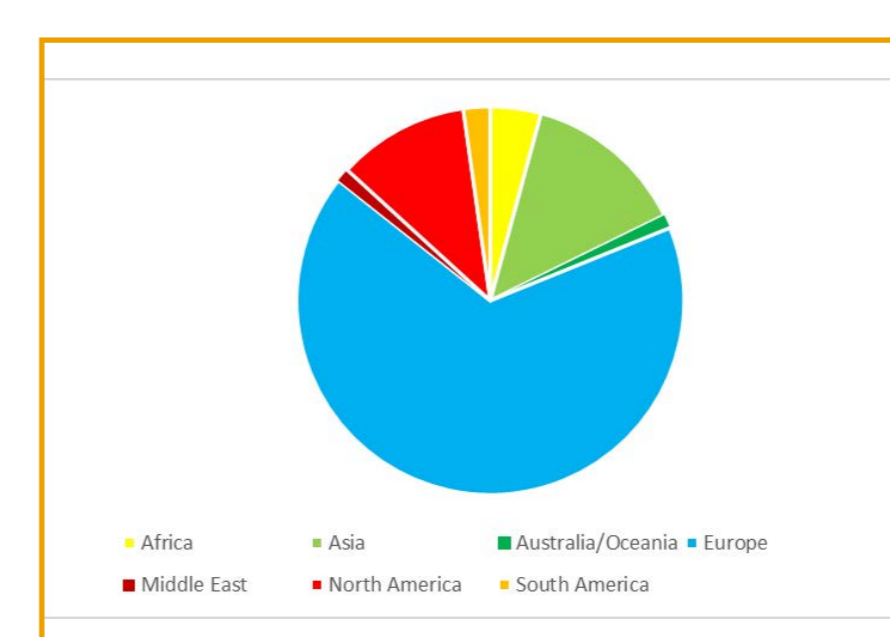


Figure 1: The percentage of survey respondents from each continent

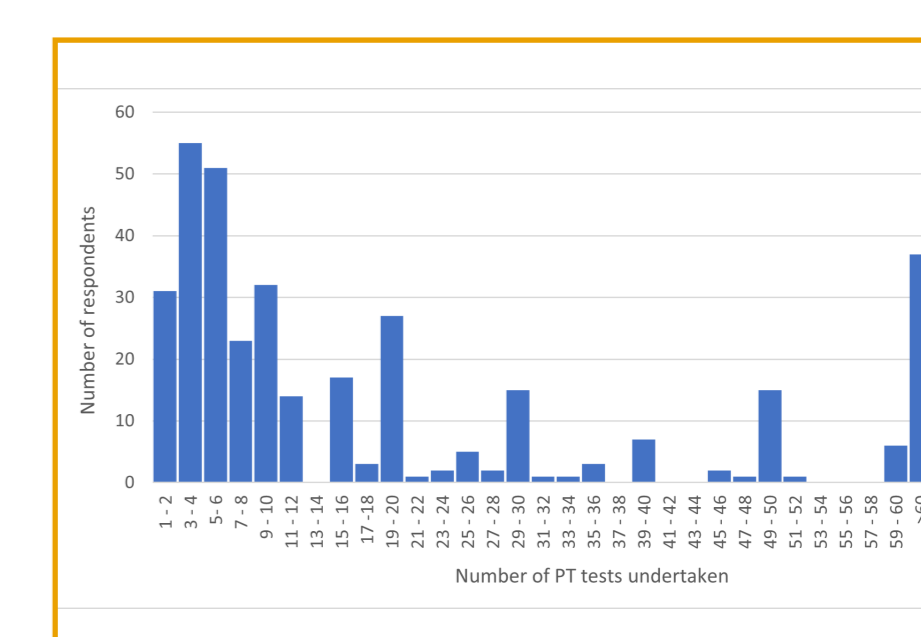


Figure 2: The number of PT tests undertaken by the respondents during the survey period

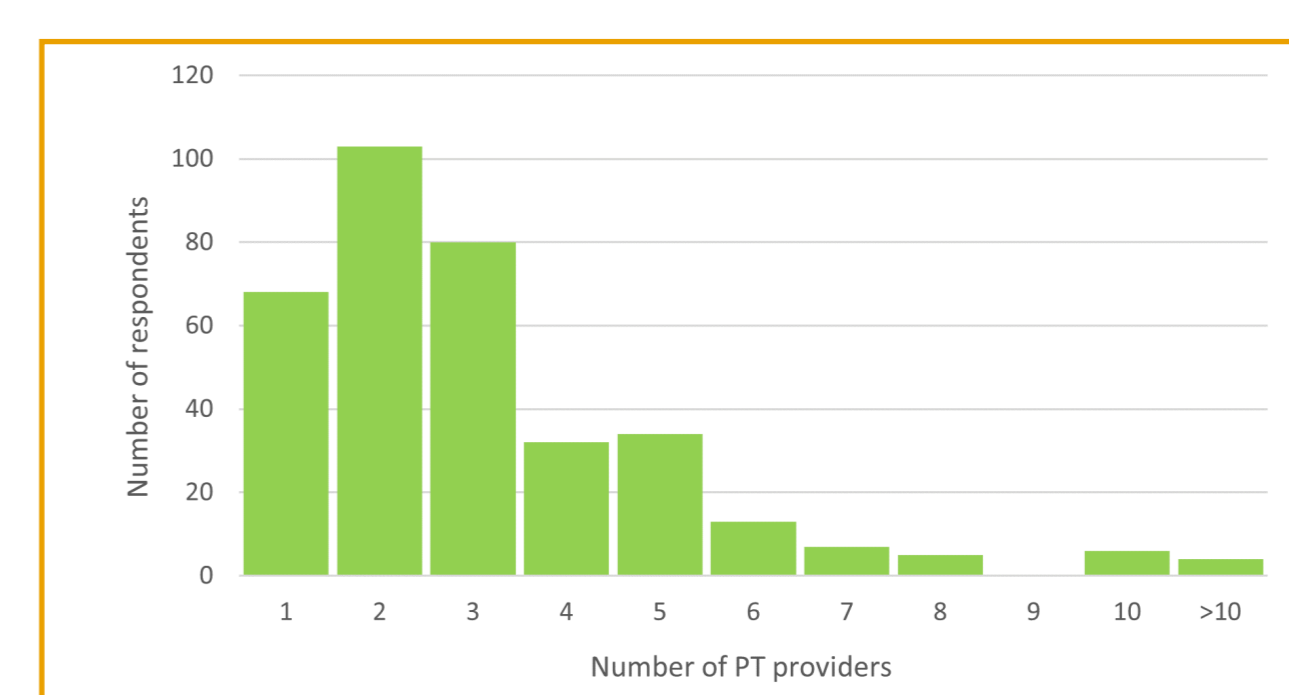


Figure 3: The number of PT providers used by the respondents during the survey period

ROOT CAUSES OF POOR PERFORMANCE

Initially the survey respondents chose from 8 categories including Other, to define the causes of their poor performance. Participants could select multiple causes, either for a single incident or to cover all of those that applied in the last three years.

The three most frequently reported causes of error were 'Human error', 'Sample preparation' and 'Equipment problem', accounting for more than 40% of the causes identified. A previous survey by Ellison and Hardcastle [1] also found the same three, broad, categories to be the most common sources of error, although in that survey the number of incidents, in descending order, was 'Sample preparation', 'Human error' and 'Equipment failure or servicing problem'.

For each choice of root cause, participants were asked to note how many occasions that had arisen. This resulted in a similar distribution of incidents, as human error and sample preparation accounted for the causes of more than 55% of the cases of poor performance reported.

The causes of each incident of poor performance was broken down further by identifying the relevant sub-categories for each of the causes. Here we provide further information on the most common causes of poor performance reported – human error, sample preparation and equipment problem. The breakdown of the categories for these three categories again showed similarities to the previous work by Ellison and Hardcastle [1], particularly where 'Sample preparation' was the cause and 'Extraction/Recovery' and 'Sample dilution to volume' were the most common sub-categories and where 'Equipment failure' was the dominant sub-category, when 'Equipment problem' was selected as the cause of poor performance.

The comparison of the responses where 'Human error' was selected as the cause of error, was more complicated. In the current survey, 'Interpretation error' was the second most commonly selected sub-category (22.1% of responses), whereas Ellison and Hardcastle [1] reported this to be only the 5th most common sub-category (8.4% of responses). The other sub-categories in the four most commonly selected, 'Transcription error', 'Limited experience' and 'Reporting instructions incorrectly followed', were all present in the four most commonly selected sub-categories in the previous work.

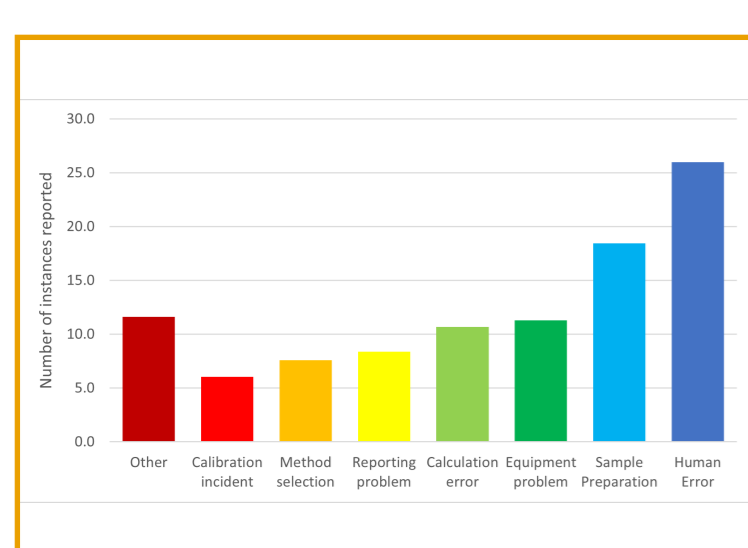


Figure 4: All causes of poor performance reported by the respondents over the survey period

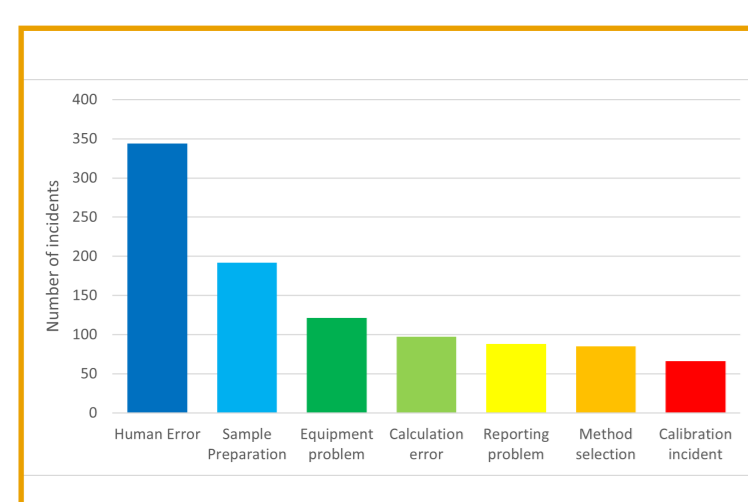


Figure 5: The number of incidents of poor performance attributed to each cause category over the survey period

HUMAN ERROR

For the incidents where human error was identified as the cause, transcription errors, interpretation errors and limited staff experience were identified as the most common sources of error.

Participants were asked to identify the actions taken to resolve the incidents of poor performance, unsurprisingly perhaps for 'Human error' the most common resolution was 'Staff training', which was stated in 200 out of 252 cases.

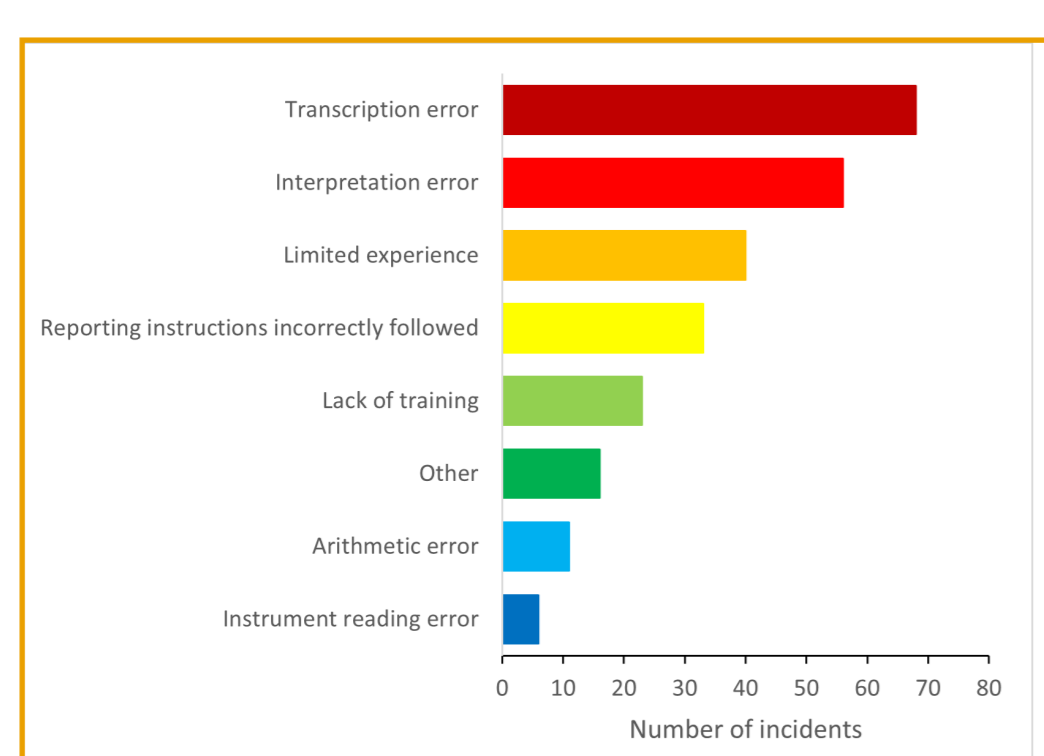


Figure 6: The number of incidents reported for each type of error, where 'Human error' was the identified cause of poor performance

SAMPLE PREPERATION

The most common sources of error, where the preparation of the PT sample was identified as the cause, were sample extraction/recovery and sample dilution to volume, which between them accounted for 60% of the responses. Other fundamental preparation steps such as weighing or grinding only accounted for a maximum of 9.5% of the identified causes for preparation errors

When the respondents were asked to list the actions which were taken to resolve the poor performance 'Staff training' was again the most selected option, included in 125 of the 192 reported incidents. Other improvement actions reported for multiple incidents were 'Introduction of a new procedure' (37 times), 'Improved method documentation' (35 times) and 'Reference materials changed' (10 times).

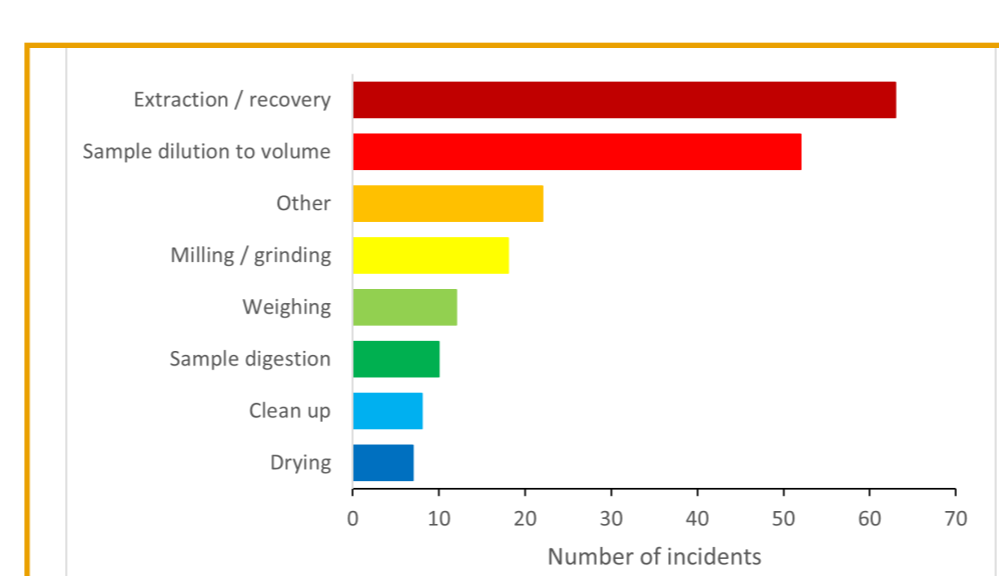


Figure 7: The number of incidents reported for each type of error, where 'Sample preparation' was the identified cause of poor performance

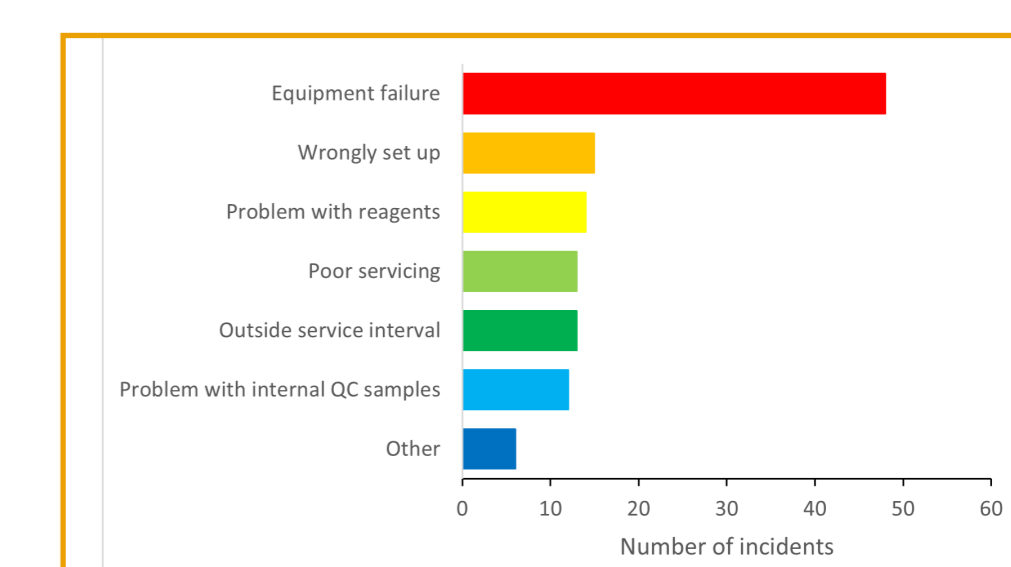
EQUIPMENT PROBLEM

Where respondents had identified an equipment problem as the cause of poor PT performance, 'Equipment failure' was overwhelmingly the most common source of error, 40% of all responses. 'Incorrect set up', 'Problems with reagents', 'Poor servicing', 'Equipment outside of the service interval' and 'Problems with internal QC' each accounted for approximately 10% of the sources of error listed by respondents.

The action taken most frequently by the respondents to resolve problems with equipment was performing additional calibration, which was included in 37 of the 121 incidents. New equipment was the second most selected improvement action, 28 occasions, of which 23 of the responses came when 'Equipment failure', 'Poor servicing' or 'Equipment outside the service interval' had been identified as the cause of poor performance.

'Re-validation of method(s)' was the third most applied improvement action, with 23 occasions, however there was no association with particular causes of poor performance.

Figure 8: The number of incidents reported for each type of error, where 'Equipment problem' was the identified cause of poor performance



ROOT CAUSES OF POOR PERFORMANCE

Respondents were asked if they had a written policy or procedure to follow for the investigation of poor performance.

Of those participants without a written policy, the majority used 'Guidance from their PT provider', in addition to any other sources of information. Those labs with a written policy/procedure had based them on information from mixture of sources, split almost equally across 'Guidance from PT provider or accreditation body and Published standards'.

The survey provides a wealth of data about the causes of PT performance which in itself, is an indicator of the potential reasons for any poor results from laboratory tests. The steps taken to rectify the issues – such as staff retraining and equipment maintenance, point to the real value of PT participation, which can be an early warning that corrective measures are needed. The data will be further analysed and shared with PT participants, indicating areas they may wish to review more regularly as part of their quality procedures.

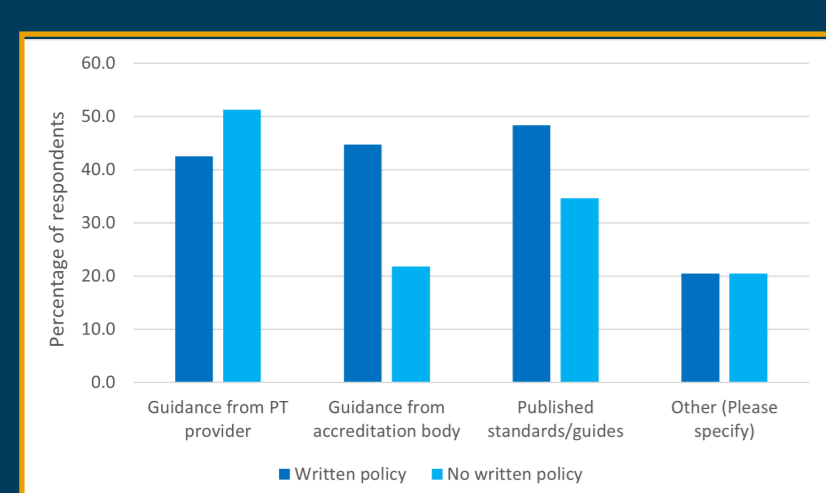


Figure 9: The source of guidance used to investigate poor performance for participants with and without a written investigation policy