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Maintaining Quality in Clinical Chemistry Laboratory

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OBJECTIVE

As part of the laboratory's effort to continuously provide accurate and reliable patient results, a quality monitoring system has been adapted into the work process. This is important in ensuring patient safety. The two monitoring systems are Internal Quality Control (IQC) and External Quality Assurance (EQA) or Proficiency Testing (PT). In addition, a method validation is required to verify that a specific assay is suitable for its intended use. One of the method validation protocols is linearity. This study aims at looking into the steps involved in these processes in ensuring that the quality in Clinical Chemistry Laboratory is maintained.

MATERIALS AND METHODS

RIPAS Hospital Clinical Chemistry laboratory's standard operating procedures (SOPs) are used in this study. Supporting data is extracted from the laboratory's quality control data management software, Unity Real Time® (Bio-Rad Laboratories). Documents from SAC-SINGLAS ISO15189:2012, CLSI and Westgard guidelines are additionally used as references.

RESULTS

There are a total of 121 tests performed in Clinical Chemistry Laboratory. There are 25 IQC materials, 14 EQA programs subscribed and 10 linearity kits in use. 52% of the IQC materials are run daily and the others are run as required in batch tests. For EQA materials, 64% are run monthly. 29% are run biyearly and 7% are run in every 4 months.

CONCLUSIONS

We highlight the steps necessary to maintain the quality of patient results and this is in accordance to recognized practice worldwide. In total, there are 216 IQC determinations. There are 1, 621 EQA reports that need to be reviewed per year.

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