

Evaluating the Implementation of a Quality Management System in the COVID-19 Diagnostic Laboratory of a Tertiary Care Hospital in Delhi

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Abstract : Introduction: COVID-19 molecular diagnostic laboratory is the cornerstone of the COVID-19 disease diagnosis as the patient's treatment and management protocol depend on the molecular results. For this purpose, it is extremely important that the laboratory conducting these results adheres to the quality management processes to increase the accuracy and validity of the reports generated. We started our own molecular diagnostic setup at the onset of the pandemic. Therefore, we conducted this study to generate our quality management data to help us in improving on our weak points. Materials and Methods: A total of 14561 samples were evaluated by the retrospective observational method. The quality variables analysed were classified into pre-analytical, analytical, and post-analytical variables, and the results were presented in percentages. Results: Among the pre-analytical variables, sample leaking was the most common cause of the rejection of samples (134/14561, 0.92%), followed by non-generation of SRF ID (76/14561, 0.52%) and non-compliance to triple packaging (44/14561, 0.3%). The other pre-analytical aspects assessed were incomplete patient identification (17/14561, 0.11%), insufficient quantity of samples (12/14561, 0.08%), missing forms/samples (7/14561, 0.04%), samples in the wrong vials/empty VTM tubes (5/14561, 0.03%) and LIMS entry not done (2/14561, 0.01%). We are unable to obtain internal quality control in 0.37% of samples (55/14561). We also experienced two incidences of cross-contamination among the samples resulting in false-positive results. Among the post-analytical factors, a total of 0.07% of samples (11/14561) could not be dispatched within the stipulated time frame. Conclusion: Adherence to quality control processes is foremost for the smooth running of any diagnostic laboratory, especially the ones involved in critical reporting. Not only do the indicators help in keeping in check the laboratory parameters but they also allow comparison with other laboratories.

Keywords : laboratory quality management, COVID-19, molecular diagnostics, healthcare

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