

IVD_19 - The importance of theoretical evaluations in the context of External Quality Assessment in Serology for Brazilian hemotherapy

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Introduction: The External Quality Assessment in Serology (EQA-Serology) is one of the tools that guarantee the quality of blood and its components. It is a proficiency test produced by Bio-Manguinhos/Fiocruz for the Ministry of Health (MS), since 2001.

Objectives: Evaluate the quality of serological tests carried out by Brazilian Hemotherapy Services (HS), to validate or not the use of blood components and prevent the transmission of infectious diseases through blood, using reference samples and Theoretical Tests (TT) to verify the technical knowledge and proficiency of the HS.

Methodology: Were analyzed the TT results from 2010 to 2023, when EQA-Serology began to be managed by the Coordination of Blood and Blood Products of the MS (CGSH/MS), considering the adherence and performance of the HS per question. In this analysis, 5 categories of knowledge were considered: Laboratory Screening (LS) – principle of serological tests; Good Practices and Legislation (GP/L) – laboratory routine activities and hemotherapy laws; Quality Control (QC) – use of internal control and participation in proficiency tests; Retro-surveillance (RS) – retrospective investigation to trace previous blood donations; Qualification and Validation (QV) – evaluation and monitoring of equipments and instruments.

Results: The evaluated period comprised 23 TTs, whose HS adherence was 86% and in only 2 TTs the adherence was lower than 70%: TT-3 (45%) and TT-11 (56%). The average HS performance for correct answers was 91%, considering 10 questions per TT and the TT-20 presented the lowest percentage of hits (81%). Regarding the composition of the evaluations, it was found that only the LS theme was present in 100% (23), the other appeared in the following order: GP/L (91%, 21); QC (69%, 16); RS (60%, 14) and QV (34%, 8). The 230 questions created followed the same logic: LS (35%, 80); GP/L (30%, 69); QC (17%, 38); RS (13%, 31) and QV (5%, 12). Regarding performance by category, the RS theme presented the lowest percentage of agreement (89%), followed by the LS, GP/L and QC themes (93% each) and the highest achievement was the QV theme (94%). On the other hand, only 4% (9) of the questions were canceled by the recourses: RS (44%, 4), LS (33%, 3) and GP/L (22%, 2), reinforcing the need to address these topics, as still generate doubts among participants.

Conclusion: The EQA-Serology TT, in addition to complying with Brazilian legislation, has contributed to the self-assessment of HS, ensuring the reliability of analyzes and the quality of transfused blood, as well as supporting health surveillance actions, providing routine performance indicators of serology laboratories around the country.

Keywords: Laboratory Proficiency Test; Quality control, Blood