The local technical validation of new plasma tube with a mechanical separator

Kamil Taha Uçar, Neval Aksoy,
Belgin Erhan, Berrin Berçik İnal

SBU Istanbul Gaziosmanpasa Taksim Education and Research Hospital, Medical Biochemistry

27th Balkan Clinical Laboratory Federation (BCLF) Congress & 30th National Biochemistry Congress (NBC) of TBS
October 27-31 2019, Belek-Antalya/Turkey

Validation/Verification

- Validation refers to the confirmation that the specific requirements for intended use or application have been fulfilled through the evaluation of objective evidence (Manufacturers).
- Verification refers to a confirmation that the specific requirements have been fulfilled by considering the provision of objective evidence (End users).

ISO 9000:2005. Quality management systems – Fundamentals and vocabulary. ISO, Geneva, Switzerland, 2005

Local technical and clinical validation

- In general, the clinical validation studies investigate only the analysis phase; however, this phase is typically considered satisfactory for laboratories.
- Studies have shown that errors in total testing process mostly arise in the preanalytical phase. Additionally, the most frequent problem that arises in the preanalytical phase is the presence of unsuitable samples.

Lippi G, et al. Diagnosis (Berl). 2019 Mar 26;6(1):25-31.

Local technical and clinical validation

- The tubes used in routine analyses are produced using various materials. These variables may affect the specifications of blood collection tubes (BCT) and the analysis results.

- As BCTs are one of the most commonly used in-vitro diagnostic devices in laboratories, they should be evaluated technically.

December 2010

GP34-A

Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline

DE GRUYTER

Clin Chem Lab Med 2016; aop

EFLM Opinion Paper

Giuseppe Lippi, Michael P. Cornes, Kjell Grankvist, Mads Nybo and Ana-Maria Simundic*, on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

EFLM WG-Preanalytical phase opinion paper: local validation of blood collection tubes in clinical laboratories

Objective

- We aimed to perform and to present the local technical validation of BD Barricor tubes.

Materials and Methods

- Apparently healthy 150 voluntary subjects were enrolled. Samples were collected in two separated tubes by a single phlebotomist. 12 quality indicators (QI) were determined for evaluation. CLSI guidelines and EFLM recommendations were considered for determining QIs.

Materials and Methods

- The existing tube, i.e., BD Vacutainer® Serum Separator Tube II was determined as the comparative tube. The new tube to be used in the laboratory, i.e., BD Vacutainer® Barricor™ Lithium Heparin Plasma Tube with Mechanical Separator was determined as the control tube.

Materials and Methods

- Difference (%) was calculated with the formula proposed by EFLM. In case of any difference of less than 1% for each indicator, the evaluated tube was considered as non-inferior.

- The formula is:

$$\left(\frac{\text{number of inadequate control tubes}}{150}\right) \text{x } 100 - \left(\frac{\text{number of inadequate comparative tubes}}{150}\right) \text{x } 100$$

Results

Indicators	Tubes		Difference (%)	Acceptable differences (<1%)
	SST™ II Advance 5.0 ml Comparative tube	Barricor™ 5.0 ml Control tube		
1. Tubes with physical defects of manufacturing	None	None	None	Ok*
2. Tubes with no vacuum or that fail to form a vacuum	None	None	None	Ok
3. Tubes not properly fitting into the blood collection device	None	None	None	Ok
4. Tubes under filling (10%)	16 samples	4 samples	-8%	Ok
5. Tubes broken or cap leaking before and after centrifugation	None	None	None	Ok
6. Tubes exterior surface contaminated with blood	None	None	None	Ok
7. Hemolysed specimens (Visual observation with colour chart)	1 paired sample	1 paired sample	None	Ok
8. Poor/incomplete barrier formation	None	1 sample	0.01%	Ok
9. Tubes including fibrin strand in sample after centrifugation	20 samples	3 samples	-11.3%	Ok
10. Tubes including fibrin mass in sample after centrifugation	2 samples	None	-1.3%	Ok
11. Tubes including red blood cell hang up to interior tube walls after centrifugation	40 samples	2 samples	-25.3%	Ok
12. Tubes including gel/foreign material/white particulate matter(WPM) in sample after centrifugation	None	37 samples†	24.6%	**Failed**

* Okay. †These samples were included in WPM.

White particulate matter

- White particulate matter (WPM) was first observed in transfusion bags.
- The analytic interference of WPM has been associated with sample aspiration at incorrect volume.

Cadamuro J, et al. Biochem Med (Zagreb). 2017;27:430-3.

White particulate matter

- According to the technical reports of BD, WPM formation is more visible in Barricor tubes as compared to other plasma samples owing to the presence of clear plasma from Barricor tubes and the visibility of WPM.
- Additionally, it was evaluated whether WPM was affected by pipetting at various distances, but no aspiration could be determined which could affect the results. Further studies are needed to investigate this aspect.

Conclusion

- Consequently, it is important to evaluate BCTs similar to other devices, and these evaluations should not be limited to the analysis phase. Technical properties that may cause problems in the preanalytical and analytical phases should also be examined.

Conclusion

- Manufacturers and end users are both responsible for evaluating BCTs. This will allow more accurate understanding of the characteristics of BCTs and increased laboratory control at the preanalytical phase.

Conclusion

- All the QIs assessed were found to be acceptable for Barricor™. However WPM, one of these 12 indicators, was detected at high levels. Therefore, it was concluded that if the BCTs are filled until the vacuum gets exhausted, they will not cause any problems during pipetting.

Thank you for your attention