

BECKMAN COULTER AU680 CARRYOVER TEST

Purpose This procedure provides instructions for performing Carryover Test on the Beckman Coulter AU680

Principle Carryover study is performed to determine if reagent cross contamination is significant to represent an analytical error that may affect patient results. It is performed during the initial evaluation of the analyzer and every 6 months thereafter with regular maintenance. It is also performed after a major repair of the analyzer's pipetting assembly.

Scope This procedure is intended for Clinical Laboratory Scientist (CLS) and Medical Laboratory Technicians (MLT) who are trained and competent in performing the Carryover testing.

Specimen storage Biorad Liquid Unassayed Chemistry Controls are stable 2°-8°C for 7 days (specifically for AST)

Equipment

- Beckman Coulter AU680 analyzer

Material and supplies

- Pipettes
- Micro cups

Reagent/s

Description	Preparation	Stability
Biorad Liquid Unassayed Chemistry Controls: Level 1 & Level 2	Controls must be brought to room temperature before use.	7 days at 2°-8°C

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Safety

All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, and the safety of others and adhering to all departmental and medical center safety policies and procedures.

- For standard precautions and safety practices in the laboratory; see LAMC-PPP-0123, specifically, but not limited to, equipment safety, proper body mechanics, sharps exposure and proper use of personal protective equipment (PPE).
- For Universal Body Substance precautions, see LAMC-PPP-0128, specifically, but not limited to, exposure to body fluids.
- For proper hand washing, see LAMC-PPP-0132, specifically, not limited to, proper hand washing.
- For proper infection control, see LAMC-PPP-0127, specifically, but not limited to, proper use of gloves.
- For proper handling of regular and infectious waste, see LAMC-PPP-0129, specifically, but not limited to, proper disposal of regular and biohazardous waste.
- For proper cleaning of work area, see LAMC-PPP-0130 – Cleaning Work Areas.
- For proper handling of chemicals and reagents, see the Chemical Hygiene Plan.
- For proper storage and disposal of chemical hazardous waste, see LAMC-PPP-0134.

Calibration

Refer to LAMC-PPP-0340 Beckman Coulter AU680 Calibration

Quality Control

Refer to LAMC-PPP-0338 Beckman Coulter AU680 Quality Control

Procedure

- Follow the steps below to run Carryover Test.

Step	Action
1	Sample carryover is determined by running ALT, AST and Creatinine (large sample size).

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2	Run all of these analytes using three replicates of a low control, one replicate of a high control and then an additional replicate of a low control. <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">Position</th> <th style="text-align: center;">Sample</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">Low Control</td> </tr> <tr> <td style="text-align: center;">2</td> <td style="text-align: center;">Low Control</td> </tr> <tr> <td style="text-align: center;">3</td> <td style="text-align: center;">Low Control</td> </tr> <tr> <td style="text-align: center;">4</td> <td style="text-align: center;">High Control</td> </tr> <tr> <td style="text-align: center;">5</td> <td style="text-align: center;">Low Control</td> </tr> </tbody> </table>	Position	Sample	1	Low Control	2	Low Control	3	Low Control	4	High Control	5	Low Control
Position	Sample												
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3	Calculate the percentage of carryover: $\% \text{ Carryover} = \frac{(\text{Result 5}) - (\text{Mean of results 1,2,3})}{(\text{Result 4})} \times 100$												
4	Percentage carryover must be within 5% of the mean of low control positions 1, 2 and 3.												

Controlled Documents

The following controlled documents support this procedure.

Document No.	Name of Documents
SCPMG QMS - 0051	Validation Policy for FDA Approved Non-Waived Test System
LAMC-PPP-0123	Safety Practices
LAMC-PPP-0127	Infection Control
LAMC-PPP-0128	Universal Body Substance Precautions
LAMC-PPP-0129	Handling of Regular and Infectious Waste
LAMC-PPP-0130	Cleaning Work Areas
LAMC-PPP-0132	Hand washing Policy
LAMC-PPP-0134	Storage and disposal of Chemical Hazardous Waste

Non-Controlled Documents

The following non-controlled documents support this procedure.

Document No.	Name of Documents
	Beckman Coulter Sample Carryover procedure for AU analyzers

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