Abbott

The following information is intended as an aid in the development of your facility's IQCP Risk Assessment and Quality Control Plan for the Alere™ hCG Combo (Serum & Urine) system. This includes all distributed Alere™ hCG Combo (Serum & Urine) systems. This document is not intended to replace the Package Insert. Any modifications to this document are the sole responsibility of the facility. Any questions about this Alere™ hCG IQCP Support Document should be directed to IQCP@Alere.com.

*All specific information here is taken from the Alere™ hCG Combo Cassette (25 mIU/mL) 115601602 09/13, Alere™ hCG Combo Cassette (20/10 mIU/mL) 1156015901 07/16 and Alere™ hCG Control Kit 70000472v1 07/14*

| FAILURE | CAUSE | FAILURE TYPE | POTENTIAL EFFECT(S) OF FAILURE | Alere™ HCG COMBO (SERUM & URINE) RISK MITIGATION FEATURES | Alere™ HCG COMBO (SERUM & URINE) LABELING INSTRUCTIONS, WARNINGS AND PRECAUTIONS | LABORATORY RISK MITIGATION | SEVERITY | FREQUENCY | LABORATORY DOCUMENTATION |
|---|---|---|---|---|---|---|---|---|---|
| Operator failure | Not following manufacturer instructions | Testing Personnel | | None | Package Insert (PI) | | | | |
| Inappropriate sample | Interfering substances with the specimen | Specimen | | None | Interfering Substances section of PI | | | | |
| | Serum not collected | Testing Personnel | | None | Specimen Collection and Preparation section of PI | | | | |
| Incorrect sampling procedure | Sample contamination with other body fluids/materials during collection | Specimen | | None | Specimen Collection and Preparation section of PI | | | | |
| | Incorrect sample type tested | Testing Personnel | | None | Specimen Collection and Preparation section of PI | | | | |
| | Inappropriate patient type collected | Testing Personnel | | None | Intended Use and Limitations section of PI | | | | |
| | Inadequate sample volume collected | Testing Personnel | | None | Directions for Use section of PI | | | | |
| | Use of external control material as a patient | Testing Personnel | | None | Directions for Use section of PI | | | | |
| | Use of non-validated sample type | Testing Personnel | | None | Intended Use, Specimen Collection and Preparation, and Limitations section of PI | | | | |
| Incorrect sample handling | Contamination after sample collection | Testing Personnel | | None | Specimen Collection and Preparation and Interfering Substances section of PI | | | | |
| | Sample stored at incorrect temperature | Environment | | None | Specimen Collection and Preparation and Directions for Use section of PI | | | | |
| | Frozen serum not thawed and mixed before testing | Testing Personnel | | None | Specimen Collection and Preparation and Directions for Use section of PI | | | | |
| | Serum not separated from blood as soon as possible | Testing Personnel | | None | Specimen Collection and Preparation section of PI | | | | |
| Operator failure | Not following PI | Testing Personnel | | None | PI | | | | |
| | Inappropriate amount of sample added | Testing Personnel | | None | Directions for Use section of PI | | | | |
| | Running a patient sample as a control or vice versa | Testing Personnel | | None | Directions for Use and Quality Control section of PI | | | | |
| Reagent handling | Improper reagent shipping temperature | Environment | | None | Storage and Stability section of PI | | | | |
| | Storage of test components outside of specified range- Temperature | Environment | | None | Storage and Stability section of PI | | | | |
| | Test device not kept in the sealed pouch before use | Testing Personnel | | None | Precautions and Storage and Stability section of PI | | | | |
| | Test device was stored in a freezer | Testing Personnel | | None | Storage and Stability section of PI | | | | |
| | Outdated reagents | Testing Personnel | | None | Expiration is printed on reagents. Precautions and Storage and Stability section of PI | | | | |
| | Not following reagent test procedure instructions | Testing Personnel | | None | Directions for Use section of PI | | | | |

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| | General Reagent Failure | Reagent | | Internal procedural controls are included in the test. A red line appearing in the control region C is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the back ground in the result area should be white to light pink and not interfere with the ability to read the test result. | Quality Control section of PI | | | | |
| Reagent Test Procedure | Failure to add patient sample | Testing Personnel | | None | Directions for Use section of PI | | | | |
| | Total assay time was not followed when testing | Testing Personnel | | None | Directions for Use section of PI | | | | |
| | Deterioration of reagent lots over time | Reagent | | Internal procedural controls are included in the test. A red line appearing in the control region C is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the back ground in the result area should be white to light pink and not interfere with the ability to read the test result. | Reagents must be stored according to the Directions for Use, Quality Control and Precautions section of PI. Expiration is printed on reagents. | | | | |
| Reading Test Results | Reading test results earlier than directed | Testing Personnel | | None | Directions for Use section of PI | | | | |
| Interpreting Results | Misinterpretation of test results | Testing Personnel | | None | Interpretation of Result section of PI | | | | |
| External Control Failure | Controls stored at 2-8° C opened and used after 90 days | Testing Personnel | | None | Storage and Stability section of hCG Control kit. | | | | |
| | Controls stored at 18-25° C used after 31 days | Testing Personnel | | None | Storage and Stability section of hCG Control kit. | | | | |
| | External control materials not brought to room temperature prior to testing | Testing Personnel | | None | Directions for Use and Quality Control section of PI and Procedure section of hCG Control kit. | | | | |
| | External control materials not mixed by gentle swirling or inversion before use | Testing Personnel | | None | Procedure section of hCG Control kit. | | | | |
| | Testing Positive control as Negative control and vice versa | Testing Personnel | | None | Directions for Use and Quality Control section of PI. | | | | |
| | Did not apply external control material to test cassette | Testing Personnel | | None | Directions for Use section of PI | | | | |
| | Outdated external controls | Testing Personnel | | None | Expiration is printed on controls. Storage and Stability section of hCG Control kit | | | | |