Summary of Analytic Considerations and Test System Monitoring

IRMA TRUPOINT® Blood Analysis System	
Potential Cause of Analytic Concern	***Automatic Control/Monitoring***
Environmental Considerations	
• Sample/environment/cartridge is below temperature during use	Yes
• Sample/environment/cartridge is above temperature during use	Yes
• Too much ambient light during use	No Effect on Instrument
• Too little ambient light during use	No Effect on Instrument
• Too much humidity during use	Yes
• Too little humidity during use	Yes
• Too much atmospheric pressure during use	Yes
• Too little atmospheric pressure during use	Yes
• Too much airflow during use	Yes
• Too little airflow during use	Yes
• Too much vibration during use	Yes
• Dust laden environment during use	Yes
• Exposure to RFI/EMI during use	Yes
• Shipping and storage issues	Yes
Operator Considerations	
• Not enough specimen when running test	Per Lab QC Competency Program
• Too much specimen when running test	Yes
• No specimen when running test	Yes
• Specimen contaminated microbially	Yes
• Specimen contaminated chemically	Yes
• Specimen contaminated with tissue fluids	Per Lab QC Competency Program
• Specimen begins to clot prior to testing/non-heparinized sample used	Per Lab QC Competency Program
• Improper anticoagulation material used	Yes
• Syringe used to inject sample is too small	Yes
• Injection of sample too fast or too slow	Per Lab QC Competency Program
• Specimen has air bubbles	Per Lab QC Competency Program
• Wrong assay cartridge used for test	Yes
• Used assay cartridge used for test	Yes
• Specimen added to cartridge prematurely	Yes
• Specimen not added to cartridge in a timely fashion	Yes
• Assay cartridge not fully inserted into instrument	Yes
• QC is not performed at required interval(s)	Automatic with Lock-out Enabled
• Patient test performed without appropriate QC	Automatic with Lock-out Enabled
• Patient ID is not entered into instrument	Automatic with Lock-out Enabled
• Operator ID is not entered into instrument	Automatic with Lock-out Enabled
• Untrained operator uses instrument	Automatic with Lock-out Enabled
• Instrument used during in-transit situations	Yes
• Incorrect entry of lot code or calibration code into instrument	Yes
• Lot code or calibration code is not entered into instrument	Per Lab QC Competency Program
• Expired cartridge used	Yes
Analysis Considerations	
• Power not available to start testing	Yes
• Power not available to complete testing	Yes
• Proper assay is not recognized by instrument	Yes
• Instrument software malfunctions	Yes
• Sensors do not function properly during test	Yes
• Detector does not function during test	Yes
• No reagent or calibrant gel during test	Yes
• Test result is inconsistent with patient's condition	Per Lab QC Competency Program

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