

Potential Risk	Control Process and Risk Mitigation Strategies
Temperature and Humidity	Meter measures the temperature at the reaction zone on test strip and compensates for temperature influences.
POCT results not recorded in patient's medical record	POCT data management ensures capture of data and transfers to patient's medical record.
Expired reagents	Barcoded test strips prevent use after expiration date.
Storage and Shipping	QC and Linearity performed on every new shipment. Temperature and humidity monitoring of storeroom.
Reagent exposure from failure to recap bottles of test strips	Meter measures strip integrity and checks for damage.
Incorrect calibration	Barcoded reagents that automatically calibrate meter with each test.
Failure to analyze or interpret controls	Software control lockout, checks control performance at defined intervals.
Wrong level control analyzed	Barcoded controls identify the level

Table 3. Risk assessment for environment and reagents.