

**Table 1 - Frequency of Quality Control Performance - Minimal Requirements  
Waived Tests Only (High and Low/Positive and Negative Controls)**

<b>TESTS</b>	<b>When Open New Lot Number (test kit)</b>	<b>When Receive New Shipment (test kit)</b>	<b>Each Day</b>	<b>Each Week</b>	<b>Each Month</b>	<b>When Instrument is Moved or when test off-site</b>	<b>When Temperature is Outside Acceptable Range<sup>6</sup></b>	<b>Document Result of Internal Control</b>
Cholestech (total chol, HDL, triglyceride, glucose)	Yes	Yes	No	No	No	Yes	Yes	NA
HemoCue B <sup>1</sup>	Yes	Yes	No	Yes	No	Yes	Yes	NA
HemoCue B Optic Check	NA	NA	Yes	No	No	Yes	NA	NA
HemoCue 201+ <sup>1</sup>	Yes	Yes	No	Yes	No	Yes	Yes	NA
HemoCue 201+ self test	NA	NA	Yes	No	No	Yes	NA	NA
Whole Blood Glucose	Yes	Yes	No	No	No	No	Yes	NA
Rapid HIV – low volume (< 25 tests per day) <sup>2</sup>	Yes	Yes	No	Yes	No	Yes	Yes	<b>Patients &amp; Controls</b>
Rapid HIV – high volume (≥ 25 tests per day) <sup>2</sup>	Yes	Yes	Yes	No	No	Yes	Yes	<b>Patients &amp; Controls</b>
Urine pregnancy <sup>3,5</sup>	Yes	Yes	No	No	No	NA	Yes	<b>Controls only (not patients)</b>
Manual Urine dipstick chemistry <sup>4</sup>	Yes	Yes	No	No	Yes	NA	Yes	NA
Automated Urine Dipstick Chemistry <sup>4</sup>	Yes	Yes	Yes	NA	NA	Yes	Yes	NA
Fecal Occult Blood	Yes	Yes	No	No	No	NA	Yes	<b>Controls only (not patients)</b>
Rapid Strep A <sup>5</sup>	Yes	Yes	No	No	Yes	NA	Yes	<b>Controls only (not patients)</b>
Hemoglobin A1c	Yes	Yes	No	No	Yes	Yes	Yes	NA
Lead Care II	Yes	Yes	No	No	No	NA	Yes	NA

- 1 Hemocue B & Hemocue 201+ - Discontinue need for control when opening a new bottle of cuvette of the same lot # received in a shipment that has already been QC'd. Other QC requirements remain unchanged.
2. Rapid HIV: low volume – on average, the laboratory tests less than 25 samples per day. High volume – on average, the laboratory tests 25 or more samples per day.
3. Urine Pregnancy : Refer to manufacturer's package insert, some manufacturers require monthly QC

4. Manual Urine Dipstick Chemistry: Diascreen – daily controls are required by the manufacturer. Laboratories using an automated urine dipstick analyzer must perform daily QC.
5. Quidel requires that QC for their Rapid Strep A and Urine Pregnancy test kits is performed every 25 tests
6. Refer to the Table 2 – Temperature requirements for specific acceptable ranges for storage of test kits and performance of testing procedure

**Table 2 - Temperature Requirements**

<b>TESTS</b>	<b>Kit Storage</b>	<b>Test Performance</b>
Cholestech (total chol, HDL, triglyceride, glucose)	48 – 86 F / 9 – 30 C	68 – 87 F / 20 – 31 C
HemoCue B <sup>1</sup>	59 – 86 F / 15 – 30 C	59 – 86 F / 15 – 30 C
HemoCue B Optic Check	NA	
HemoCue 201+ <sup>1</sup>	59 – 86 F / 15 – 30 C	59 – 86 F / 15 – 30 C
HemoCue 201+ self test	NA	
Whole Blood Glucose	59 – 86 F / 15 – 30 C	59 – 86 F / 15 – 30 C
Rapid HIV – low volume (< 25 tests per day) <sup>2</sup>	46 – 86 F / 8 – 30 C	64 – 86 F / 18 – 30 C
Rapid HIV – high volume (≥ 25 tests per day) <sup>2</sup>	46 – 86 F / 8 – 30 C	64 – 86 F / 18 – 30 C
Urine pregnancy <sup>3,5</sup>	40 – 86 F / 4 – 30 C	64 – 86 F / 18 – 30 C
Urine dipstick chemistry <sup>4</sup>	64 – 86 F / 18 – 30 C	64 – 86 F / 18 – 30 C
Fecal Occult Blood	59 – 86 F / 15 – 30 C	59 – 86 F / 15 – 30 C
Rapid Strep A <sup>4</sup>	68 – 86 F / 20 – 30 C	68 – 86 F / 20 – 30 C
Hemoglobin A1c	36 – 86 F / 2 – 8 C	59 – 86 F / 15 – 30 C
Lead Care II	60 – 80 F / 15 – 27 C	60 – 80 F / 15 – 27 C