

Potential Risk	Control Process and Risk Mitigation Strategies
Interfering substances	Meter not subject to interference. Refer to evaluation report.
Lipemia, Hemolysis	<ol style="list-style-type: none"> 1. Triglycerides <1800mg/dl no interference. 2. Wipe away first drop of blood with dry gauze; avoid milking and squeezing of puncture site.
Hematocrit	10%–65% acceptable. System checks for variations and compensates.
Disease contraindications: poor circulation, diabetic ketoacidosis, trauma	Review and education of meter limitations.
Incorrect sample volume	System detects adequate sample volume.

Table 1. Risk assessment for samples, from the St Elizabeth Medical Center glucose meter validation study.