 Franciscan Health System St. Anthony Hospital Gig Harbor, WA St. Clare Hospital Lakewood, WA St. Elizabeth Hospital Enumclaw, WA St. Francis Hospital Federal Way, WA St. Joseph Medical Center Tacoma, WA	<h1 style="color: blue;">PROCESS</h1>	DOCUMENT NUMBER J-PR-HEM1539-00
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VARIANT HG-ADVISOR REVIEW CRITERIA		

BACKGROUND

This criteria is specific for use with BioRad Variant II-Turbo HbA1c Kit – 2.0 and Hg-Advisor software program. Chromatograms are visually reviewed from the Variant database screen prior to releasing results.

CHROMATOGRAM – VISUAL REVIEW ACCEPTANCE CRITERIA


1. Base line is flat, unbroken, stable between specimens. No ramping present.
2. A1c and Ao peak are present.
3. A1c peak shape: sharp, symmetrical, not rounded. Peak does not significantly overlap into adjacent windows. The grey-shaded peak mimics the original peak outline.
4. Reject any non-flagged sample which does not pass the visual check, and repeat, if indicated.

HG-ADVISOR FLAGGED SPECIMEN REVIEW

Use the following chart to review samples which are held on the Flagged specimen list.

HG- ADVISOR ERROR	HG-ADVISOR RECOMMENDED ACTION	SUPPORTIVE ACTIONS
TOTAL AREA OUT OF RANGE (1.0 million to 3.5 million) A1c is not reportable if outside this range.	REPEAT / MANUALLY DILUTE Choose a recommended dilution from the two listed in the column to the right.	<u>Low Area Count:</u> Make 1:150 dilution (10uL sample and 1.5 ml diluent) <u>High Area Count:</u> Make 1:600 dilution (5uL sample and 3.0 ml diluent)
MISSING Ao PEAK MISSING HGA1c PEAK A1c is not reportable if the Ao and/or A1c Peak is missing.	REPEAT SAMPLE Check sample for proper mixing or for volume. Review chromatogram for possible homozygous variant hemoglobin.	If no Ao/ A1c peak is present after repeat, result in Cerner as SEE COM, using the VAR1 footnote. Do not TRT to PAML.
A1C UNDER LIMIT Lower reportable limit = 3.9%	REVIEW CHROMATOGRAM If chromatogram is acceptable, report in Cerner as <3.9%	
A1C OVER LIMIT Upper reportable limit = 19%.	REVIEW CHROMATOGRAM If chromatogram is acceptable, report in Cerner as >19.0%	

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Related Documents	Forms	

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A1A, A1B PEAK OVER LIMIT: A1A: >2.6% A1B: >3.5%	REVIEW CHROMATOGRAM Leave the test pending and give copy of chromatogram to MT-coordinator or TIC to review.	Elevated A1a, A1b peaks should be reviewed for A1c peak interference, or for the presence of a variant Hgb.
UNKNOWN PEAK OVER LIMIT UNK: >0.9% (1 st and 2 nd)	REVIEW CHROMATOGRAM If peak is less than 2%, do not repeat. Result may be reported if good chromatography.	Note: If more than 2 Unknown peaks are present, suspect a system problem and troubleshoot for air or ramping.
UNKNOWN PEAK OVER LIMIT UNK: (3 rd or 4 th)	REVIEW CHROMATOGRAM Repeat sample after troubleshooting for system problem.	If more than 2 Unknown peaks are present, suspect a system problem and troubleshoot for air or ramping.
F PEAK OVER LIMIT: HGB F: >25%	REVIEW CHROMATOGRAM A1c result not reportable. Report as SEE COM using the VAR3 footnote.	Do not send sample to PAML.
P3/P4 PEAK OVER LIMIT: P3, P4 >10%	REVIEW CHROMATOGRAM TRT to PAML if over 10%	PAML wc/ts: 950/975. *
LA1C PEAK OVER LIMIT LA1c >4%	REVIEW CHROMATOGRAM Hold sample at room temp to allow conversion to A1c. Repeat at 24 hours.	If LA1c is over 4% on repeat at 24 hours, report A1c result as SEE COM and attach the VAR2 footnote.
HGB VARIANT? C-VARIANT? Variant Window present C-Window present	REVIEW CHROMATOGRAM No need to repeat sample. TRT sample to PAML.	PAML wc/ts: 950/975. ** Samples performed after a C or Variant peak should be repeated if carry-over is present.

* Note: Specimens TRT'd to PAML are taken to specimen processing and placed in the ALL PAML rack for refrigerated specimens. Place in rack by last digit of Accession number.

**Note: Hg S, E, D elute in the Variant-Window. Hg-C elutes in the C-Window. The Variant II-Turbo HgA1c – 2.0 Kit has not yet received FDA clearance for reporting A1c results for samples with Hg C and Hg Variants.

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