

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 50D0889256	(X3) Date Survey Completed 04/07/2023
Name of Provider or Supplier Virginia Mason Franciscan Health Bellevue	Street Address, City, State 11695 Ne 4th St, Bellevue, WA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the Laboratory Director (LD/TC) on March 23, 2023, the laboratory failed to retain quality control analyzer printouts for the Abbott PocH-100i for at least 2 years. The findings include: 1. A random record review of four patient reports conducted in 2021 and 2022, revealed that the laboratory did not have documentation of the PocH-100i QC printouts for one (1) of the four (4) months reviewed. Month Year June 2021- No analyzer printed records January 2022 September 2022 November 2022 2. The LD /TC confirmed by an interview on March 23, 2023 at 3:15 pm, the lack of retention of the quality control printouts for June of 2021. 3. The laboratory reports performing 40 Hematology patient specimens annually.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a record review of the laboratory's policy and procedures and an interview with the laboratory director/ Technical Consultant (LD/TC) on March 23, 2023, the</p>

laboratory failed to establish procedures to assess competency for the laboratory Technical consultant and laboratory testing personnel following 42 C.F.R. 493.1413 Subpart M. The findings include: 1. The laboratory did not have a policy or procedure for accessing the laboratory Technical Consultant (TC) competency. 2. The laboratory procedures did not include all of the required elements as listed in Subpart M, 493.1413 (8) (i-vi) for personnel competency. Three of the six critical elements were not included in the personnel competency assessments. Missing Elements: iii. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records v. Assessment of previously analyzed specimens, internal blind testing samples, or external proficiency testing vi. Assessment of problem-solving skills. 4. Six (6) of nine (9) testing personnel did not have semi-annual or annual competency assessments performed. 5. Three (3) of nine (9) testing personnel did not have semi-annual competency assessments performed. 6. The laboratory director confirmed by interview on March 23, 2023, the lack of establishing acceptable policies and procedures for assessing testing personnel and TC competency which included all elements as required by 42 C.F.R. 493.1413 Subpart M. 7. The laboratory reports performing approximately 2,620 patient tests annually.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:
Based on a record review of the laboratory Quality Assessment records and of general laboratory systems quality assessment reviews for American Proficiency Institute (API) proficiency testing (PT) failures, and an interview with the laboratory Director /Technical Consultant (LD/TC) on March 23, 2023, the laboratory failed to document corrective actions training taken for PT failures with the appropriate staff who had performed the PT. The findings include: 1. For PT event failures the laboratory's corrective action was to retrain staff. Year Event Analyte Score 2021 1 Neutrophil 60% 2021 2 Neutrophil 0% 2021 2 Hgb A1C 20% 2021 3 Hgb A1C 20% 2022 1 pCO2 0% 2022 1 pO2 20% 2022 1 pH 20% 2022 3 WBC Diff 27% 2022 3 Lymph 20% 2022 3 Monocyte 20% 2022 3 Neutrophil 20% 2. The laboratory did not have documentation of staff training for PT failures.. 3. The laboratory Director confirmed by interview on March 23, 2023 at 11:00 am, the lack of documentation of staff training and quality assessment of the effectiveness of the training provided. 4. The laboratory reports performing 2,620 patient tests annually.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on a record review of the laboratory's Quality Control (QC) records, Maintenance logs, calibration Verification reports, and interview with the laboratory Director/Technical Consultant (LD/TC) on March 23, 2023, the laboratory failed to monitor and evaluate the overall quality of the analytic systems prior to testing of patient specimens. The findings include: 1. The laboratory failed to approve and follow QC policy's and procedures. see D5407, and D5447 2. The laboratory failed to perform and document Maintenance as required by the manufacturer. See D5429 3. The laboratory failed to perform Calibration verification twice annually as required. See D5439

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manuals and interview with the laboratory Director /Technical Consultant (LD/TC) on March 23, 2023, the laboratory failed to have an approved procedure manual signed, and dated by the current laboratory director. The findings include: 1. Review of the laboratory's procedure manual revealed the lack of a cover page or documentation for each procedure with the current LD/TC signature and date of approval. 2. The LD/TC confirmed by interview on March 23, 2023, at 2:15 pm the laboratory procedure manual approval signature page was missing. 3. The laboratory records indicate the laboratory performs 2,620 patient tests annually.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on maintenance record review and interview with the laboratory director (LD /TC) on March 23, 2023, the laboratory failed to perform and document maintenance as defined by the manufacturer for the Sysmex PochH-100i, the ABAXIS piccolo, and Cepheid GenExpert Express analyzers on which non-waived testing is performed. The findings include: 1. A review of maintenance manuals for 2021 and 2022 revealed that maintenance was not documented on maintenance logs for the above analyzers on each day of patient testing. June 2021 January 2022 September 2022 December 2022 a. For the Sysmex PochH-100i, the laboratory had no documentation of background checks for during the start-up for each day of patient testing per the manufacturers instruction, or the cleaning of the analyzer weekly for June 2021, January, September, and December of 2022. b. The laboratory failed to document any maintenance on the Abbott Piccolo analyzer for 2021 and 2022. 2. The daily maintenance logs for June 2021, January 2022, September 2022, and December 2022 were not reviewed and

signed by the LD/TC or thier designee for the PocH-100i as indicated on the maintenance logs. 3. The laboratory director confirmed by an interview on March 23, 2023, at 3:15 pm, the failure to document maintenance as required by the manufacturer. 4. The laboratory reports performing 40 Sysmex PocH-100i, (hematology), 1012 ABAXIS Piccolo Xpress Chemistry, and 372 Cephid GenExpert Express bacteriology tests annually.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's calibration Verification (Cal/Ver) records and an interview with the laboratory Director/ Technical Consultant (LD/TC) on March 23, 2023, the laboratory failed to perform and document verification of analyzer accuracy twice annually for the Abbot iSTAT and the Abaxis Piccolo. The findings include: 1. For the above analyzers, (which do not have an internal 3-point calibration), the laboratory failed to perform and document calibration verification for one of two required annual calibration verifications performing non-waived testing. Abaxis Piccolo Chemistry: year Cal/Ver Performed 2020 07/2020 2021 03/09/2021 2022 09 /20/2022 Abbott iSTAT Blood Gas: 2021 03/09/2021 2022 09/14/2022 2. The LD/TC confirmed by interview on March 23, 2023, at 3:15 pm, the laboratory did not perform calibration verifications twice annually. 3. The laboratory reports performing 1,012 Piccolo chemistry and 1,199 iSTAT patient tests annually.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory quality control (QC) logs, and an interview with the laboratory Director/Technical Consultant (LD/TC) on March 23, 2023, the laboratory failed to document performing QC at least once a day patient specimens are assayed or examined for the Abbott iSTAT, using two control materials of different concentrations. The findings include: 1. QC record review for the Abbott iSTAT for 2021, and 2022, revealed that the laboratory did not perform QC on each day of patient testing. 2. The laboratory had developed an Individual Quality Control Plan (IQCP) for the Abbott iSTAT. 3. The IQCP was not complete, it did not include an assessment element of the plan, and was not signed and dated by the laboratory director. 4. The laboratory Director confirmed by an interview on March 23, 2023, at 2:15 pm, the lack of QC records for the ABX Poch 100i, and the lack of an acceptable IQCP for the Abbott iSTAT. 5. The laboratory reports performing approximately 1,199 iSTAT tests annually.

D5775

COMPARISON OF TEST RESULTS
 CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
 Based on record review and interview with laboratory director (LD/TC) on March 23, 2023, the laboratory failed to define the relationship twice annually between the iSTAT and the Abaxis Piccalo analyzers for the analyte creatinine during survey years 2021 and 2022. The findings include: 1. Review of the laboratory quality assessment records and quality control records for the testing years 2021 and 2022, revealed a lack of documentation of twice annual correlation between the non-waived testing performed on the Abbot iSTAT analyzer and the Abaxis Piccalo for the analyte Creatinine. 2. The LD/TC confirmed by interview on March 23, 2023, at 3:30 pm, the laboratory had not performed the correlation studies between the two different analyzers for the analyte creatinine. 3. The laboratory records indicate the laboratory performs 947 creatinine patient tests annually.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
 Based on record review and interviews with the laboratory Director/Technical Consultant (LD/TC) on March 23, 2023, the laboratory Director failed to meet the qualification requirements of 493.1405 of this subpart and to provide overall management and direction in accordance with 42 C.F.R. 493.1407. The findings

Include: 1. The laboratory Director failed to ensure that policies and procedures were established for the performance and documentation of the laboratory quality control program. See D6030 2. The laboratory Director failed to ensure policy and procedures for personnel training and competency assessments were maintained to meet 42 C.F.R. 493.1413 Subpart M. see D6032

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's training and competency records and an interview with the laboratory Director/ Technical Consultant (LD/TC) on March 23, 2023, the laboratory Director failed to ensure that policies and procedures are established for monitoring individuals who conduct analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The findings include: 1. Review of nine (9) testing personnel semi-annual and annual competency records for 2021 and 2022, revealed the lack of review or approval by the LD/TC identifying the competency of the testing personnel (TP), and for which tests each individual is authorized to perform. 2. Review of the laboratory policies and procedures revealed that lack of delegation of Authority to another to perform training and competency assessments of TP in place of the Laboratory Director. 3. Review of semi-annual and annual competency records for 2021 and 2022, revealed the lack of competency assessment for testing personnel in accordance with 42 C.F.R. 493.1413 for the six (6) elements required. See D5209 4. The laboratory Director confirmed by interview on March 23, 2023, at 11:30 am, the lack of competency procedures/policies that included the six (6) elements for a competency review, review and signature of the LD/TC. 5. The laboratory reports performing 2,620 patient tests annually.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures

each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of testing personnel training and competency records, and interview with the laboratory Director/ Technical Consultant (LD/TC) on March 23, 2023, the laboratory Director failed to specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and post-analytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required before reporting patient test results. The findings include: 1.

Review of nine (9) out of nine (9) testing personnel (TP) training and competency records revealed the lack of LD/TC review or approval for the testing methodology in which the TP performed patient testing for the years 2021, and 2022. 2. Review of TP training and competency records indicated direct observation (DO) performed of the TP performing each test. The DO records did not include the LD/TC authorization for the testing performed, or whether supervision was required. 3. The LD/TC confirmed by an interview on March 23, 2023, at 2:15 pm, the lack of written authorization TP for the testing performed, if supervision was required, and the lack of LD/TC signature of approval and date. 4. The laboratory reports performing 2620 patient tests annually.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's competency records for 2021 and 2022, and interview with the laboratory Director/Technical Consultant (LD/TC) the technical consultant failed to include all elements as required by CMS in 42 C.F.R. 493.1413 Subpart M to establish competency of testing personnel. The findings include: 1. Review of nine (9) testing personnel (TP) competency records revealed the lack of including review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records for TP during 2021, and 2022 for initial, semi-annual, and annual competencies. See D5209.