Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	50D0632166	07/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Mason Franciscan Health Bainbridge Island	1344 Wintergreen Ln Ne, Bainbridge Island, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from American Proficiency Institute (API), and interview with the laboratory Technical Consultant (TC), the laboratory failed to have signed attestation records for four (4) of eight (8) records in 2024 and four (4) of twelve (12) in 2023. Findings included: 1. A review of 4 of 8 API PT records in 2024 did not include signed attestation records by the Laboratory Director (LD). 2024 Records include: a) 1st event for Microbiology b) 2nd event for Microbiology c) 2nd event for Chemistry d) 2nd event for Hematology 2. A review of 4 of 12 API PT records in 2023 did not include signed attestation records by the Laboratory Director (LD). 2023 Records include: a) 1st event for Chemistry b) 1st event in Coagulation/Hematology c) 2nd event for Microbiology d) 3rd event for Chemistry 3. An interview with the TC on 07/24/2024 at 12:30 pm confirmed that attestations forms were not signed by day of survey. 4. The laboratory reports performing 1934 Bacteriology, Chemistry, Mycology, and Hematology tests annually.
D5006	MYCOLOGY CFR(s): 493.1203 If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on observation during the laboratory tour, a lack of verification and maintenance records, and an interview with the Dermatology supervisor, the laboratory failed to establish and follow written policies and procedures to assess personnel competency, failed to twice annually verify the accuracy of the testing of fungal elements using potassium hydroxide (KOH), and failed to perform and document maintenance for the Olympus microscope. See D5209, D5217, D5401, and D5429.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of competency assessment (CA), policies and procedures, and interview with the Technical Consultant (TC), the laboratory failed to establish a CA policy and procedure to assess Testing Personnel (TP) competency. Findings include: 1. Review of CA records for 2023 and 2024 revealed that the TC failed to review and complete CA for three (3) of three (3) Laboratory TP and six (6) of six (6) Point of Care TP. See D6046. 2. Request for policies and procedures revealed that the laboratory did not have an established policy in place for performing CAs. 3. Interview with the TC on 07/24/2024 at 12:30 pm confirmed that the laboratory did not have a policy and procedure in place. 4. The laboratory reports performing 1934 Bacteriology, Chemistry, Mycology, and Hematology tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation during the laboratory tour, a lack of verification records, and an interview with the Dermatology lead and Technical Consultant (TC), the laboratory failed to have a system for verifying the accuracy of the testing for fungal elements using potassium hydroxide (KOH). Findings include: 1. Laboratory tour revealed an Olympus microscope and KOH reagent used for fungal elements/mycology in the dermatology section of the facility. 2. Review of documentation revealed that the laboratory failed to have any verification records for fungal elements/mycology. 3. Interview with the Dermatology lead on 07/23/2024 at 1:00 pm confirmed that fungal elements/mycology identification is being performed and that there is no documentation of verifying the accuracy of testing. 4. Interview with the TC on 07/23 /2024 at 1:00 pm confirmed that the laboratory was not aware that fungal elements /mycology were being performed at the facility. 5. The laboratory reports performing 30 mycology tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation during a laboratory tour, document review, and interview with the Dermatology lead and Technical Consultant (TC), the laboratory failed to have written procedures for fungal element/mycology testing. Findings include: 1. Laboratory tour revealed a microscope used for fungal elements/mycology in the dermatology section of the facility. 2. Document review of Centers for Medicare & Medicaid Services (CMS) Form CMS-116 revealed that the laboratory failed to document mycology non-waived testing. 3. Document request revealed that the laboratory failed to have written procedures for fungal elements/mycology testing. 4. Interview with the Dermatology lead on 07/23/2024 at 1:00 pm confirmed that fungal elements/mycology identification is being performed and no procedures are available. 5. Interview with the TC on 07/23/2024 at 1:00 pm confirmed that the laboratory was not aware that fungal elements/mycology were being performed at the facility. 6. The laboratory reports performing 30 mycology tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on document review of Sysmex pocH-100i Quality Control (QC) and error log, policies and procedures, and interview with the Technical Consultant (TC), the laboratory failed to have a procedure for corrective action when control results fail. Findings include: 1. Review of Sysmex pocH-100i QC and error log records from July 1, 2024 through July 23, 2024 revealed that the laboratory failed to document corrective action on July 12, 2024 at 7:28 a.m. for QC05 (level 2) when QC was out of acceptability. 2. Review of the QC procedure "Sysmex pocH-100i Performing Liquid QC Standard Work" revealed that the laboratory failed to include a policy

	/procedure for documenting corrective actions taken if QC fails to meet the laboratory's established criteria for acceptability. 3. Review of the "Sysmex pocH-100i Analyzer Procedure" failed to include a process for documenting all corrective actions taken if the quality control (QC) did not meet the laboratory's acceptability criteria. The troubleshooting controls listed in the procedure are as follows: 1) Repeat quality controls. 2) Verify that quality control ranges are properly defined on the analyzer. 3) Change reagents. 4) Refer to the Sysmex Operator's Manual. 5) Call Point of Care and/or Sysmex Technical Support. 4. Interview with the laboratory TC confirmed on 07/24/2024 at 12:30 pm that there was no corrective action policy or procedure when calibration or control results fail to meet the laboratory's criteria for acceptability. 5. The laboratory reports performing 1934 Bacteriology, Chemistry, Mycology, and Hematology tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, storage requirements, and interview with the Testing Personnel 1 (TP-1), the laboratory failed to monitor the temperature of i-STAT PT /INR cartridges in Room 14 (Central Pod) room temperature and Room 170 (Pharmacy) refrigerator. Findings included: 1. During a tour of Room 14 (Central Pod) on 07/23/2024 at 2:00 pm, fourteen (14) i-STAT PT/INR cartridges were stored at room temperature with no documentation of temperature ever being monitored. 2. During a tour in Room 170 (pharmacy) on 07/24/2024 at 1:00 pm, 1 box of i-STAT PT /INR cartridges were stored in the pharmacy pHcbi refrigerator with no record of the laboratory monitoring the temperature. 3. Review of the manufacturer's storage specifications located on the box revealed acceptable storage temperature of 2C to 8C when stored refrigerated or 18C to 30C if stored at room temperature and cartridges must be at room temperature 18C to 30C or 64F to 86F prior to use. 4. In an interview with TP-1 on 7/23/2024 at 2:15 pm confirmed that the temperature in Room 14 and the Pharmacy refrigerator located in Room 170 were not being monitored by the laboratory. 5. The laboratory reports performing 1359 PT/INR tests annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on document review of PocH-100i verification and interview with the Technical Consultant (TC), the laboratory failed to verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population for the PocH-100i hematology analyzer. Findings include: 1. Document review of PocH-100i Hematology verification of performance revealed that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population from date of onboarding, August 2022. 2. Interview with the TC on 7/24/2024 at 12:30 pm confirmed that the reference intervals used are from the Seattle laboratory location. 3. The laboratory reports performing 1618 Hematology 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 observation during a laboratory tour, lack of equipment and maintenance records, and interview with the Dermatologist lead and Technical Consultant (TC), the laboratory failed to perform and document maintenance for the Olympus microscope. Findings include: 1. Laboratory tour revealed an Olympus microscope used for fungal elements/mycology in the dermatology section of the facility. 2. Request for documentation revealed that the laboratory failed to have any maintenance records for performing fungal elements/mycology using the Olympus microscope. 3. Interview with the Dermatology lead on 07/23/2024 at 1:00 pm confirmed the use of the Olympus microscope for fungal elements/mycology identification performed and no maintenance records available. 4. Interview with the TC on 07/23/2024 at 1:00 pm confirmed that the laboratory was unaware that fungal elements/mycology was being performed at the facility. 5. The laboratory reports performing 30 mycology tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) procedure, Sysmex pocH-100i maintenance Records from 07/01/2024 through 07/23/2024, and interview with

	staff, the laboratory failed to document corrective actions taken when quality control (QC) did not meet the laboratory's criteria for acceptability. Findings include: 1. Review of Sysmex pocH-100i maintenance records from 07/01/2024 through 07/23 /2024 revealed that the laboratory failed to document corrective actions and the assessment of patients obtained in the unacceptable QC run, and since the last acceptable QC run for 1 of 1 patient on 07/11/2024 at 10:23 am to determine if patient testing results were affected. See D5783. 2. Review of maintenance records for the Sysmex pocH-100i from 01/01/2024 through 02/06/2024 and December 2023 revealed that the laboratory failed to document corrective actions for three (3) of fourteen (14) out of range (30-85%) humidity from 01/01/2024 through 02/06/24 and four (4) of twelve (12) in December 2023. Out-of-range dates include: a) 01/09/2024 b) 01/15/2024 c) 01/16/2024 d) 12/09/2023 e) 12/11/2023 f) 12/12/2023 g) 12/12 /2023 5. Interview with the laboratory Technical Consultant on 07/23/2024 at 12:30 pm confirmed that the laboratory could not provide documentation of corrective actions taken during the period above. 6. The laboratory reports 1618 hematology tests performed annually.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a document review of Quality Control (QC) for Sysmex pocH-100i Serial Number (SN) G7203, maintenance records 07/01/2024 to 07/23/2024, the pocH-100i Quality Control (QC), and interview with the Technical Consultant (TC) the laboratory failed to document corrective actions and evaluate test results from the last acceptable test run when quality control (QC) failed to meet the laboratory's criteria for acceptability. Findings include: 1. Review of Sysmex pocH-100i QC and error log printouts revealed that QC05 (level 2) was out of acceptability, and repeat QC was performed on 07/12/2024 at 07:28 am. 2. Review of Sysmex pocH-100i maintenance records from 07/01/2024 through 07/23/2024 revealed that the laboratory failed to document corrective actions and the assessment of patients obtained in the unacceptable QC run, and since the last acceptable QC run for 1 of 1 patient on 07/11 /2024 at 10:23 am to determine if patient testing results were affected. 3. Interview with the laboratory's Technical Consultant on 07/23/2024 at 12:30 pm confirmed that the laboratory had taken no corrective action and no evaluation of patient test results from the last acceptable test run. 4. The laboratory reports 1618 hematology tests performed annually.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

	This STANDARD is not met as evidenced by: Based on surveyor review of policies and procedures, patient reports, and interview with the testing personnel and the laboratory director, the laboratory failed to follow its policy for reporting life threatening test results "critical values" as staff failed to notify the requesting physician for one (1) of one (1) critical D-Dimer results reviewed. Findings include: 1. Review of policy and procedures revealed that a value greater than six hundred (>600) nanograms per milliliter (ng/mL) was a critical value, and critical call documentation was required. 2. Review of one (1) of (1) critical D-Dimer result of 1270 ng/mL for patient-2190B on 09/23/2022, revealed that the laboratory failed to document the critical result per the laboratory's policies and procedures. Documentation included "Report to...MA-C of ...ARNP." 3. Review of the laboratory procedure titled "Critical Call Documentation" required all fields to be recorded: a) Critical result: Name of the test(s) with critical result(s) b) Called to: Name of provider notified c) Date/time reported: Press F5 for timestamp d) Tech: Your Operator ID or initial. 4. Testing personnel TP-1 confirmed on 07/24/2024 on 10: 03 am that the critical result "was not documented correctly" per their policy and procedures. 5. The laboratory reports performing 1934 Bacteriology, Chemistry, Mycology, and Hematology tests annually.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the personnel document, policy for personnel requirements, and interview with the Technical Consultant (TC), the laboratory failed to have a TC who meets the qualification requirements of 493.1411. Findings include: See D6035 and D6046
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's

	degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of the personnel documents, policy for personnel requirements, and interview with the Technical Consultant (TC), the laboratory failed to have a TC who meets the qualification requirements of 493.1411. Findings include: 1. Review of personnel documents for TC-1, revealed that TC-1 did not meet the qualifications in accordance with 493.1413. 2. Review of the "Virginia Mason Laboratory document Technical Consultant Delegation Policy" under the "Qualification" section revealed that the TC failed to meet the qualifications per the laboratory's policy, which states, "Meets 42 CFR standard 493.1411 Specifications." 3. Interview with The TC confirmed on 07/24/2024 at 12:30 pm that they did not earn a bachelor's degree in chemical, physical, biological science, or medical technology from an accredited institution. 4. The laboratory reports performing 1934 Bacteriology, Chemistry, Mycology, and Hematology tests annually.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on document review of testing personnel (TP) competency assessments (CA) and an interview with the Technical Consultant (TC), the TC failed to review and grade TP CAs from 2022 through 2024, and failed to perform and evaluate CA for fungal elements using potassium hydroxide for one TP. Findings include: 1. Document review of TP-1 2022 Competency Assessment failed to have competencies reviewed and graded by TC: a) 11/01/2022 i-STAT (International Normalized Ration (INR), cardiac Troponin I (cTNI)) competency failed to have TC's review and quiz graded. b) 11/01/2022 Cepheid GeneX competency failed to have TC's review and quiz graded. c) 11/01/2022 Abaxis Piccolo Xpress competency failed to have TC's review and quiz graded. 2. Document review of TP-2 2023 Competency Assessment failed to have competencies reviewed and graded by TC: a) 2023 Sysmex PocHi-100i competency failed to have TC's review and quiz graded. b) 2023 Cepheid GeneX

	competency failed to have TC's review and quiz graded. c) 2023 i-STAT (International Normalized Ration (INR), cardiac Troponin I (cTNI) competency failed to have TC review and quiz graded. d) 2023 Abaxis Piccolo Xpress competency failed to have TC's review and quiz graded. 3. Document review of TP-3 2024 Competency Assessment failed to have competencies signed and graded by TC: a) 2024 Sysmex PocHi-100i competency failed to have TC review and quiz graded. b) 2024 Cepheid GeneX competency failed to have TC review and quiz graded. c) 2024 i-STAT (International Normalized Ration (INR), cardiac Troponin I (cTNI) competency failed to have TC review and quiz graded. d) 2024 Abaxis Piccolo Xpress competency failed to have TC review and quiz graded. 4. Document review of six (6) of six (6) medical assistants performing INR Point of Care testing (POCT) revealed that TC did not review and grade POCT quizzes. 5. Document review for CA for fungal elements using potassium hydroxide for dermatology one (1) of one (1) was not performed from 2022 to 2024. 6. Interview with TC on 07/24/202024 at 12:30 pm confirmed the above findings. 7. The laboratory reports performing 1934 Bacteriology, Chemistry, Mycology, and Hematology tests annually.