Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	50D2126255	07/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sea Mar Community Health Centers - Federal Way Med	31405 18th Ave S, Federal Way, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of the U.S. Food & Drug Administration (FDA) database, CoaguChek XS prothrombin time international normalized ratio (PT/INR) test instructions for use (IFU), laboratory's PT/INR procedure, patient records, and interview with the testing personnel (TP), the laboratory failed to follow the manufacturer's instructions for waived testing by performing PT/INR testing beyond the monitoring of warfarin therapy for two (2) out of four (4) patient samples in July 2024. Findings include: 1. A review of the FDA database revealed that the CoaguChek XS PT system is Clinical Laboratory Improvement Amendments (CLIA) waived test. 2. A review of the CoaguChek XS PT IFU revealed that "the manufacturer CoaguCheck XS system is intended for the use by professional healthcare providers for quantitative PT testing for monitoring warfarin therapy." 3. A request for test reports from July 2024 revealed that the laboratory reported two (2) out of four (4) patients outside of the manufacturer's recommended usage for patients not on warfarin therapy. See below: Date PT Order Diagnosis 7/11/2024 806511713 Epistaxis 7/23/2024 836380283 Easy Bruising 4. A review of the laboratory's "CoaguChek XS Analyzer Procedure for PT/INR" revealed that the laboratory performed testing to assist in diagnosis. 5. An interview with TP-1 on 7/24/2024 at 2: 33 pm confirmed that the laboratory performed PT/INR test on "patients not on warfarin therapy and for diagnosis if a provider suspects coagulation issues." 6. The laboratory reports performing 49 PT/INR 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 review of the laboratory's Microscopy Examination of Urinary (UA) Sediment policy/procedure, Wet Preparation policy/procedure, and interview with the Technical Consultant (TC), the laboratory failed to ensure a step-by-step procedure to calculate (Grade) quantitative UA sediments observed (View), Findings included: 1. Review of the policy/procedure 400.03.02 Microscopy Examination of the Urinary Sediment revealed that the laboratory failed to include a system to calculate (Grade) UA sediments observed (View). See below: a) Normal Crystals/Hpf Grade View Neg none 1+ few 2+ mode 3+ many 4+ loaded b) Bacteria/Hpf Grade View Neg none 1+ occ 2+ small 3+ mode 4+ large/loaded c) Renal/Trans ep/Hpf Grade View Neg 0-5 >5 Sheets of clumps =Present d) Squamous ep/Lpf Grade View Neg none 1+ occ 2+ few 3+ mode 4+ many e) Yeast/Trich/Sperm *no field indicated Grade View Neg none 1+ occ 2+ few 3+ mode 4+ many 2. A review of the policy/procedure 400.05.004 "Wet Preparation Testing" revealed that the "Reporting of Results" failed to include a system to calculate (Grade) Wet Preperation constituents observed (View). See below: Reporting results in Hpf: a) Clue Cells: Negative, Few, Moderate, Many b) Yeast: No yeast observed or No yeast Seen, Budding, Pseudohyphae; 1+ through 4+ (Few, Rare, Some, Moderate, Many, Loaded or full Field) c) Leukocytes: None, 1+ through 4+ (Few, Rare, Some, Moderate, Many, Loaded or Full field) d) Bacteria: 1+ through 4+ (Few, Rare, Some, Moderate, Many, Loaded or full Field) f) Epithelial Cells: 1+ through 4+ (Few, Rare, Some, Moderate, Many, Loaded or full Field) 3. An interview with the Laboratory TC on 07/25/2024 at 1:00 pm confirmed that the policy /procedures listed above did not include a system for a step-by-step procedure for reporting quantitative constituents. 4. The laboratory reports 22 Wet Preperation and 27 UA sediment tests annually. Key: Hpf = High power field Tran. = Transitional Ep = epithelial Trich = Trichomonas
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation during a laboratory tour and an interview with the Technical Consultant (TC), the laboratory failed to ensure reagents did not exceed their expiration. Findings include: 1. Observation during a laboratory tour on 7/25/2024 at 10:15 am showed the following expired reagents in the laboratory testing room. a) Deionized water (DiH2O) expired 4/30/2023. b) Normal Saline Solution (NSS) expired 7/14/2024 used for Wet preparation testing. 2. Interview with the TC on 7/22 /2024 at 2:00 pm confirmed that expired reagents were available for patient use. 3. The laboratory reports performing 8,697 tests annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation during a laboratory tour, review of urine quality control (QC) policy/procedure, and interview with laboratory staff, the laboratory failed to define the appropriate operating settings for the Unico powerspin LX centrifuge when performing urine (UA) microscopic analysis testing. Findings include: 1. Observation during a laboratory tour on 7/25/2024 at 10:15 am revealed that the laboratory's Unico powerspin LX centrifuge speed setting was at 2250 RPM. 2. Document review of the laboratory's policy and procedure, "Microscopy Examination for Urinary Sediment," revealed the centrifuge setting for UA microscopic testing was set at 1500 RPM. 3. Review of Unico powerspin LX centrifuge operating settings revealed that urine speed ranges from 2000 to 2200 RPM. 4. Interview with testing personnel on 7/25 /2024 at 10:35 am confirmed that the RPM was outside the laboratory's established limit. 5. The laboratory performs 27 Urine microscopic tests annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review of urine quality control (QC) results and Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopic Control Level 1 and 2, and interview with the laboratory staff, the laboratory failed to ensure that results of QC material

	met the laboratory's acceptability before reporting Urine Microscopic/Sediment results. 1. Review of QC results and Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopic Control Level 2 Abnormal Level Lot: 225482 Exp:2025-03-31 revealed that the laboratory failed to document bacteria results and reported epithelial cells when not listed as an analyte in the QC material. See results below for Level 2 QC (key below): Date Analyte QC ** Lab result: 1/8 RBC 1-17/2-25 3-6 1/8 WBC 1-9/1-13 10-15 1/8 Cast None NA 1/8 Cry Present 15-25 1/8 Bact Present NR* 4/9 RBC 1-17/2-25 4-6 4/9 WBC 1-9/1-13 10-20 4/9 Cast None NA 4/9 Cry Present 10-15 4/9 Bact Present NR* 5/30 RBC 1-17/2-25 4-7 5/30 WBC 1-9/1-13 10-15 5/30 Cast None NA 5/30 Cry Present 10-25 5/30 Bact Present NR* 6/17 RBC 1-17/2-25 5-10 6/17 WBC 1-9/1-13 10-20 6/17 Cast None NA 6/17 Cry Present 20-30 6/17 Bact Present NR* 6/17 Epi N/A 0-3* 6/21 RBC 1-17/2-25 4-7 6/21 WBC 1-9/1-13 5-10 6/21 Cast None NA 6/21 Cry Present Many 6/21 Bact Present NR* 6/24 RBC 1-17/2-25 4-7 6 /24 WBC 1-9/1-13 5-10 6/24 Cast None NA 6/24 Cry Present 30-40 6/24 Bact Present NR* 6/24 Epi N/A 0-4* 7/8 RBC 1-17/2-25 4-8 7/8 WBC 1-9/1-13 10-15 7/8 Cast None NA 7/8 Cry Present 15-30 7/8 Bact Present Present 7/8 Epi N/A Present* * = Results that our outside of the expected QC range ** = QC ranges for ~0.5 / ~1.0 mL supernatant volumes. NR = Not reported NA = Not applicable 2. Interview with testing personnel on 07/24/2024 at 1:00 pm confirmed that the QC results were not in range. 3. The laboratory reports performing 27 urine microscopic results 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 Mindray BC-3600 Auto Hematology corrective action log, and interview with staff, the laboratory failed to document corrective actions taken when quality control (QC) and instrument background did not meet the laboratory's criteria for acceptability. Findings include: 1. Review of BC-3600 Auto Hematology corrective action log from 12/26/2023 through 01/04/2024 revealed that the laboratory failed to document corrective actions performed when QC failed. See Laboratory's documentation below: a) 12/26/23 Background/ QC failed prescribed trouble shooting from probe cleansing/zap flush/changed diluents and primed reagents but QC fails. MECO (Mindray Technical Support) called for the problem. No CBC done. b) 12/27/2023 Background pass but QC fails. No CBC done. c) 12/28/2023 Background pass but QC fails. No CBC done. MECO will come Friday (12-29-23) d) 12/04/2024 Finally get machine going. Background/QC passed and in ranges. 2. Interview with the TP stated that QC corrective action "document only major instrument issues" and steps taken to repeat QC were not documented. This confirmed that QC steps were not documented at 07/25/2024 at 1:00 pm. 3. The laboratory performs 1674 hematology tests 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 Mindray BC-3600 Auto Hematology corrective action records, and interview with the testing personnel (TP) the laboratory failed to lab failed to evaluate patient test results from the failed QC to the last acceptabel test run. Findings include: 1. Review of BC-3600 Auto Hematology corrective action long revealed that the laboratory failed to evaluate patient test results since the last unacceptable test run. Corrective actions documented by the laboratory listed below: a) 12/26/23 Background/ QC failed prescribed trouble shooting from probe cleansing /sap flush/changed diluents and primed reagents but QC fails. MECO (Mindray Technical Support) called for the problem. No CBC done. b) 12/27/23 Background pass but QC fails. No CBC done. c) 12/28/23 Background pass but QC fails. No CBC done. MECO will come Friday (12/29/23) d) 12/04/2024 Finally get machine going. Background/QC passed and in ranges. 2. Interview with the TP stated "we document only major instrument issues." TP confirmed that the laboratory failed to evaluate patient results since the last unacceptable run. 3. The laboratory performed 1674 annually.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on record review of urine quality control (QC) results, Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopic Control Level 1 and 2, and interview with the Testing Personnel (TP-1), TP-1 failed to ensure that QC met the laboratory's acceptability before reporting test results. See D5481.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interveiw with the Techincal Consultant (TC), the

	laboratory failed to have a Laboratory Director (LD) that met the qualification requriments of 493.1443 high complexity. See D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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) Be a doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of procedure Post Vasectomy Sperm Examination, U.S. Food & Drug Administration (FDA) database, Laboratory Director (LD) credentials, and interview with the Technical Consultant (TC), the laboratory failed to have a Laboratory Director (LD) that met the qualification requirements 493.1443 high complexity. Findings include: 1. Review of the laboratory's procedure, "Post Vasectomy Sperm Examination," revealed that reporting results "include the number of spermatozoa seen at low power field (LPF) if they are motile when sperm are seen on the initial view." 2. Review of the U.S. Food and Drug Administration (FDA) database revealed that "All manual semen analyses (count and morphology)" are categorized as high-complexity testing. 3. Review of LD credentials revealed that the LD does not qualify as a High Complexity LD. 4. Interview with the TC confirmed on 09/05/2024 at 08:44 am that the LD does not qualify as a High Complexity LD. 5. The laboratory reports 6 post-vasectomy tests annually.