

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0867504	(X3) Date Survey Completed 11/05/2025
Name of Provider or Supplier Oregon Urology Institute	Street Address, City, State 2400 Hartman Lane, Springfield, OR	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the anti-microbial susceptibility (AST), using the technique Minimum Inhibitory Concentration (MIC's) in the Beckton Dickinson (BD) Micro-Scan Instrument guide, review of the Clinical Micro-Stat procedure manual and interview with the Technical Supervisor (TS #2), the laboratory failed to ensure a standardized inoculum was used when preparing suspensions of microorganisms for MIC testing as the Micro-Scan testing system manual requires. Findings include: 1. See D5507</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.</p>

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's procedure manual for Clinical Micro-Stat microbiological testing performed on human specimens for antimicrobial sensitivity testing (AST's) by minimum inhibitory concentration method (MIC's) performed on the Beckton Dickinson (BD) Micro-Scan instrument and interview with TS #2, the laboratory failed to ensure the manufacturers instructions were followed regarding turbidity when making inoculation substrate for testing the microbial isolate for MIC's. Finding include: 1. The user's guide for the BD Micro-Scan instrument, in regards to preparation of inoculum for the MIC's states "the inoculum density must be equivalent to a 0.5 McFarland Turbidity Standard". 2. Upon review of the laboratory's procedure manual for Microbiology (compiled by the contracted Microbiology service - Clinical Micro-Stat), the laboratory failed to ensure the Micro-Scan manufacturers requirement of a turbidity standard for all inoculum / emulsions that were to be tested for MIC's was indicated in their procedure for MIC's and available for use by trained microbiology testing personnel (TP), including either a BD turbidity meter or a 0.5 McFarland standard. 3. Interview with TS #2 for Clinical Micro-Stat at 12:30 pm confirmed that the emulsions made for MIC's were not compared to a 0.5 McFarland standard or by using the BD Microscan Turbidity Meter, with a reading of 0.08 - +/- 0.02 prior to inoculating the MIC plate for the BD Micro-Scan instrument. 4. The laboratory reports performing 3500 moderate and high complexity microbiological assays annually.

D5445

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(1)(2)(g)

(d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:
 Based on review of the Individual Quality Control Plan (IQCP) for microbiological culture media end user quality control (QC) submitted during survey and interview with the Tecnical Supervisor (TS #2), the laboratory failed to include the five (5) required risk assessment elements in their end user QC IQCP, and failed to include any written documentation of what was reviewed for this IQCP according to their Quality Assurance Plan (QAP) for this IQCP, each calendar year it was signed off. Findings include: 1. Upon request for evidence of end user QC for microbiological media used to test human specimens for pathogenic microorganisms, none could be produced from the last end user QC event dated 05/05/2024. 2. Review of the IQCP procedure in the laboratory procedure manual revealed an incomplete IQCP Risk Assessment, including only two (2) of the five (5) required elements and lack of any written documentation to support the Quality Assurance Plan (QAP) review, signed and dated yearly from February 2019 through February 2025, by the Laboratory Director (LD) and Technical Consultant (TC #1). 3. Interview with the TS #2 post survey 11/10/2025 at 0930 am by phone, revealed the contracted microbiology staff

were unaware of any end user microbiological media IQCP procedure. 4. The laboratory reports performing 3500 Microbiological assays annually.

D5507

BACTERIOLOGY
CFR(s): 493.1261(b)(c)

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the antimicrobial susceptibility testing (AST) procedure in place during survey, using the technique Minimum Inhibitory Concentration (MIC's) for the Beckton Dickinson (BD) Micro-Scan instrument and interview with Technical Supervisor (TS #2), the laboratory failed to ensure a standardized inoculum was used when preparing suspensions of microorganisms for MIC testing as the BD Micro-Scan MIC testing system manual requires. Findings include: 1. The BD Micro-Scan instrument manual states "The final turbidity (of the inoculum) should be the equivalent to a 0.5 McFarland standard". 2. There is also a turbidimetric device offered by Micro-Scan to use in place of the 0.5 McFarland standard. For specific detail see D5441 #3 in findings. 3. When interviewed as to which method Clinical Micro-Stat testing personnel (TP) used to determine turbidity of inoculum for MIC's, TS #2 responded at 12:20 pm that neither were in use nor did they have a 0.5 McFarland standard or BD Micro-Scan turbidity meter on site for use. 4. The lab reports performing 3500 moderate and high complexity microbiological assays annually.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on review of the Individual Quality Control Plan (IQCP) in place for moderate and high complexity Microbiology testing and interview with Technical Supervisor (TS #2) for Clinical Micro-Stat, the Laboratory Director (LD) failed to ensure that the IQCP for end user Quality Control (QC) on microbiological media, used in the testing of patient specimens for pathological microorganisms, contained all the required Risk Assessment elements described in CFR 493.1256(d) prior to approval. Findings include: 1. Upon request for proof of end user QC on their microbiological culture media from two (2) microbiologists on site during survey, both stated at 12:15 pm, "We do not do that anymore". Review of the last documented end user QC record showed a date of 05/05/2024. 2. Interview with TS #2 at 12:20 pm confirmed that end user QC on their microbiological culture media had ceased to be performed after 05/05/2024, "because Washington (state) told us we do not have to do it anymore". 3.

Review of the procedure manual presented by testing personnel (TP #1), at 1:30 pm, revealed a partial IQCP for the required end user QC of microbiological media, which includes storage requirements. 4. Upon review of the incomplete IQCP risk assessment for end user QC, it was noted that the reagent portion of the IQCP risk assessment required Blood agar plates (BAP) to be stored at 2 - 8 degrees Celcius. Review of the manufacturers package insert states the same for storage of BAP's and most media. Direct observation of BAP's in a cabinet at room temperature (RT), where cultures are set up by nursing staff was noted during survey. 5. Phone interview with TS #2 from contracted service Clinical Micro-Stat on 11/10/2025 at 0940 am revealed that the blood agar plates are often left at room temperature in the cabinet over the weekend. 5. CFR 493.1256(d) specifies that a minimum of five (5) elements are assessed when composing the IQCP, including: Specimen, Test System, Reagent, Environment and Testing Personnel. The partial IQCP presented for review during survey listed two (2) of the five (5) required elements of risk assessment, being Reagents and Test System. 6. Review of the sign off sheet for the partial IQCP presented for review reflected the LD's signature/date and the lead RN's signature/date (also Technical Consultant (TC #1) on CMS form 209) and revealed the following: a. Review sheet cover page of the three (3) page document reads "Hardy Diagnostics Culture Media Quality Control Plan". The table contains evidence of signature by the present LD and TC #1. b. The signatures/initials by both the LD and TC#1 and comments are as follows: 1. 10/24/2019 Reviewed 2. 02/12/2020 Reviewed 3. 02/09/2021 CLIA survey review, no changes 4. 02/10/2022 Review, no changes 5. 02/08/2023 Review, no changes 6. 02/09/2024 Review, no changes 7. 02/21/2025 Reviewed, no changes 6. The approval signature page is for an incomplete IQCP. 7. Phone interview with TS #2 from contracted service Clinical Micro-Stat on 11/10/2025 at 0930 am revealed that she was unaware of an IQCP in place for the microbiological media in use at this facility. 8. The facility reports performing 3500 moderate and high complexity assays annually.