Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2011330	03/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Oss Hospital	1861 Powder Mill Road, York, PA	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records, laboratory policies, and interview with Technical Supervisor (TS), the laboratory failed to test PT samples the same number of times that it routinely tests patient samples for 1 of 3 API Immunology/Immunohematology PT events performed in 2025. Findings: 1. On the day of survey, 3/25/2026 at 10:30 am, review of API PT records for Antibody Screen (ABSC) testing revealed the laboratory tested the following PT samples in duplicate for 1 of 3 API Immunology/Immunohematology PT events performed in 2025: - API Event 3 2025: Sample # Ser-11 and SER-14 2. Review of the laboratory's LAB-09 Proficiency Testing Program Policy revealed, "4. Proficiency test samples will be tested in exactly the same manner as patient samples are tested. a. Samples will not be tested in duplicate unless that is the protocol followed for patient samples. b. Samples will only be repeated (e.g with panic values) if a patient sample would have been repeated under the same circumstances." 3. The laboratory failed to provide a policy that included the protocol for repeat testing for ABSC examinations performed on patient samples. 4. The TS (CMS-209, dated 03/11/2026) confirmed the above findings on 03/25/2026 at 03:00 pm.
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures, patient transfusion records, and interview with the Technical Supervisor (TS), the facility failed to follow the established policy to ensure positive identification of blood products and the intended recipient for 3 of 4 units of red blood cells (RBC) transfused on 03/17/2025. Findings: 1. The facility policy titled CN-10 Blood Administration and Transfusion Reaction Policy stated, " Blood Administration: At the bedside, the RN is responsible for: Checking patient's first and last name, patient's date of birth, and OSS Orthopaedic Hospital armband number from patient's wristband with name and date of birth and OSS Orthopaedic armband number on the transfusion tag attached to the blood product and verify with another RN/Physician or Mid-level Provider. Having two (2) RNs or RN/Provider sign where indicated on the transfusion tag before hanging the blood product, one of whom is the RN that is administering the blood product. The RN/Provider who administers the blood is responsible for completing the transfusion tag for each unit of blood transfused." 2. On the day of the survey, 03/25/2026 at 01:30 pm, review of patient transfusion records (Transfusion Tag) revealed the facility failed to ensure the person that started the transfusion documented the following requirements for positive patient/product identifcation for 3 of 4 RBC units (W270125500426, W270125501261, W2070125501280) transfused on 03/17/2025: - I have established the identity of the patient. - ABO/Rh type and unit number on this form agree with unit tag. - Name and Hospital number on this form agree with those on the patients wristband. - I have checked the expiration date on the unit. - Transfusion instruction sheet explained and given to patient. - Transfusion Difficulties - Signature/Co-signature and Date 3. The TS (CMS 209, dated 3/11/2026) confirmed the findings above on 03/25/2026 at 03:30 pm.
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 lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to establish and follow a competency assessment (CA) procedure to assess the competency of 1 of 1 Technical Supervisor (TS), 1 of 1 Technical Consultant (TC) and 2 of 2 General Supervisor (GS) for their supervisory responsibilities performed from 3/25/2024 to 3/25/2026. Findings Include: 1. On the day of survey, 3/25/2026 at 11:00 am, the laboratory failed to provide a competency assessment procedure to assess the competency of 1 of 1 TS (CMS 209, personnel #2), 1 of 1 TC (CMS 209, personnel #2) and 2 of 2 GS (CMS 209, personnel #2 and #3) for their supervisory responsibilities performed in the laboratory from 3/25/2024 to 3/25/2026. 2. The laboratory failed to provide CA records for TS #1, TC #1, and GS #1 and #2 (CMS 209, dated 3/11/2026) for their supervisory responsibilities performed from 3/25/2024 to 3/25/2026. 3. The laboratory performed 106,953 examinations in 2025 (CMS 116 reported volume, dated). 3. The LM confirmed the findings above on 3/25/2026 at 11:10 am.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

	(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the laboratory Manager (LM), the laboratory failed to establish performance specifications before reporting patient test results when modifying an FDA-cleared/approved test system for platelet count (PLT) examinations performed on 1 of 1 CDS M-Series hematology analyzer using sodium citrate anticoagulant from 3/25/2024 to 3/25/2026. Findings include: 1. Review of the CDS M-Series manufacturer's instructions for use stated, "Whole blood should be collected in K2 or K3EDTA anticoagulant and peritoneal, pleural, and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended." 2. On the day of the survey, 3/25/2026 at 2:45 pm, the laboratory failed to provide documentation for the performance specifications established when performing PLT counts using sodium citrate anticoagulant (blue top tube) on 1 of 1 CDS M-Series hematology analyzer using sodium citrate anticoagulant from 3/25/2024 to 3/25/2026. 3. The LM (CMS 209, personnel #2, dated 3/11/2026) confirmed the findings above on 3/25/2026 3:00 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 calibration verification (Cal Ver) records and interview with the

	Laboratory Manager (LM), the laboratory failed to include a high level material near the upper limit of the laboratory's approved reportable range (RR) at least once every six months when the Cal Ver was performed on 1 of 1 Medica Easy RA routine chemistry analyzer from 3/25/2024 to 3/25/2026. Findings include: 1. On the date of survey, 3/25/2026 at 12:30 pm, review of Cal ver records revealed the laboratory failed to include a high level material near the upper limit of the approved RR at least once every six months when the Cal Ver was performed on 1 of 1 Medica Easy RA routine chemistry analyzer for the following analytes from 3/25/2024 to 3/25/2026. -Albumin: verified range 1.43 - 5.43 g/dL, RR 0.4 - 7.0 g/dL -Carbon Dioxide: verified range 5.7 - 39.4 mEq/L, RR 2.3 - 45.0 mEq/L -Calcium: verified range 4.6 - 14.9 mg /dL, RR 1.0 - 15.0 mg/dL -Creatinine: verified range 0.2 - 13.3 mg/dL, RR 0.2 - 20.0 mg/dL -Direct Bilirubin: verified range 0.50 - 10.90 mg/dL, RR 0.06 - 10.00 mg/dL -Glucose: verified range 27 - 580 mg/dL, RR 2 - 600 mg/dL -Total Bilirubin: verified range 0.46 - 11.70 mg/dL, RR 0.08 - 20.0 mg/dL -Total Protein: verified range 1.5 - 8.9 g/dL, RR 0.1 - 10.0 g/dL -Urea Nitrogen: verified range 5.5 - 69.2 mg/dL, RR 1.0 - 70.0 mg/dL -Uric Acid: verified range 2.0 - 12.1 mg/dL, RR 0.11 - 12.00 mg/dL 2. The LM (CMS 209, personnel #2, dated 3/11/2026) confirmed the finding above on 3 /25/2026 at 1:45 pm.
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. This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the Laboratory Manager (LM), the laboratory failed to evaluate twice a year the relationship between test results using different methodologies for platelet (plt) count examinations (hematology) performed for 2 of 2 years from 3/25/2024 to 3/25/2026. Findings include: 1. On the day of the survey, 3/25/2026 at 2:45 pm, the laboratory failed to provide documentation for the evaluation of the relationship between test results using different methodologies for the following hematology examinations performed for 2 of 2 years from 3/25/2024 to 3/25/2026: - Plt count using Ethylenediaminetetraacetic acid (EDTA) anticoagulant vs Sodium Citrate anticoagulant. 2. The LM (CMS 209, personnel #2, dated 3/11/2026) confirmed the findings above on 3/25/2026 at 3:00 pm.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the the Laboratory Manager (LM), the Technical Consultant (TC) failed to assess the competency of 1 of 6 testing

	personnel (TP) that performed moderate complexity microbiology examinations from 3/25/2024 to 3/25/2026. Findings include: 1. On the day of survey, 3/25/2026 at 11:30 am, the laboratory failed to provide competency assessment records for 1 of 6 TP (CMS 209, TP #6, dated 3/11/2026) that performed Methicillin-resistant Staphylococcus aureus (MRSA) examinations (microbiology) from 3/25/2024 to 3/25 /2026. 2. The LM (CMS 209, personnel #2, dated 3/11/2026) confirmed the findings above on 3/25/2026 at 11:30 am.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, American Proficiency Institute (API) proficiency testing (PT) records, and interview with the Technical Supervisor (TS) , the laboratory director (LD) failed to ensure that all API PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for 4 of 18 API PT testing events for hematology, chemistry, and microbiology testing performed in 2024 and 2025. Findings Include: 1. The laboratory's LAB-09 Proficiency Testing Program Policy stated, " Evaluation of Results: 1. All Proficiency Test reports must be reviewed and signed by the Lab Director." 2. On the day of the survey, 03/25/2026 at 11:30 am, review of API PT records revealed the LD failed to review and sign the PT test reports received for the following 4 of 18 API PT testing events performed in 2024 and 2025: -API 2024 Hematology/Coagulation - 1st Event -API 2024 Microbiology - 2nd Event -API 2024 Hematology/Coagulation - 3rd Event -API 2025 Chemistry - Core - 3rd Event 3. The TS (CMS 209, dated 3/11/2026) confirmed the findings above on 03/25/2026 at 12:30 pm.