Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1104444	(X3) Date Survey Completed 09/19/2023
Name of Provider or Supplier Rothman Orthopaedic Specialty Hospital Lab	**Street Address, City, State** 3300 Tillman Drive, Bensalem, 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
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 the College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory director (LD), the LD/designee failed to sign 1 of 3 CAP PT attestation statement documents for chemistry testing performed in 2022. Findings Include: 1. On the day of the survey, 09/19/2023 at 10:15 am, review of the CAP PT records revealed that the following 1 of 3 CAP PT attestation statements reviewed were not signed by the LD or designee in 2022: - Critical Care Blood Gas with Chemistry, i-STAT Survey: AQI-B 2022 2. The LD confirmed the findings above on 09/19/2023 at 02:00 pm.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with technical consultant #2 (TC), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests were performed from 09/20/2022 through the day of survey. Findings include: 1. The PA regulation (5.23(b)(1) states: "A general supervisor who meets all

	the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. On the day of the survey, 09/19/2023 at 10:30 am, further review of the laboratory personnel report (PA State), and personnel credentials revealed the laboratory failed to ensure the PA regulations were met regarding having a quailifed supervisor on site during all normal scheduled working hours in which tests were performed from 09/20 /2022 to 09/19/2023. 3. Review of the CMS 116 revealed the laboratory performs patient testing 7 days a week, 24 hours a day. 4. TC #2 confirmed the findings above on 09/19/2023 at 02:00 pm.
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 lack of documentation and interview with technical consultant #2 (TC), the laboratory failed to perform calibration verification at least once every six months for 4 of 4 Abbott iSTAT analyzers from 09/23/2022 to the date of the survey. Findings include: 1. On the date of the survey, 09/19/2023 at 01:19 pm, the laboratory could not provide calibration verification records for the required analytes tested on 4 of 4 Abbott iSTAT analyzers from 09/23/2022 to 09/19/2023. 2. TC #2 confirmed the finding above on 09/19/2023 at 02:00 pm.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on lack of documentation and interview with technical consultant #2 (TC), the laboratory failed to inspect the alarm system for 1 of 1 refrigerator used for storage of blood products to ensure an audible alarm was activated at the appropriate temperatures from 09/23/2022 to the date of the survey. Findings Include: 1. On day of survey, 09/19/2023 at 09:47 am, the laboratory could not provide an established policy for inspecting the alarm system for 1 of 1 refrigerator used for storage of blood products to ensure an audible alarm was activated at the appropriate temperatures from 09/23/2022 to 09/19/2023. 2. The laboratory could not provide documentation of the alarm checks performed for 1 of 1 refrigerator from 09/23/2022 to 09/19/2023. 3. TC #2 confirmed the findings above on 09/19/2023 at 02:00 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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with technical consultant #2 (TC), the laboratory failed to have a system that twice a year evaluates the relationship between 4 of 4 Abbott iSTAT analyzers used for chemistry and hematolgy testing from 09/23 /2022 to the day of the survey. Findings include: 1. On the day of the survey, 09/19 /2023 at 11:00 am, the laboratory could not provide documentation of the biannual comparison of test results for 4 of 4 Abbott iSTAT analyzers used for chemistry and hematology testing from 09/23/2022 to 09/19/2023. 3. The laboratory performed 712 hematology examinations and 5,696 chemistry examinations in 2022 (CMS-116 annual volume). 4. TC #2 confirmed the findings above on 09/19/2023 at 02:00 pm.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, lack of documentation, and interview with technical consultant #2 (TC), the laboratory director (LD) failed to ensure that quality control (QC) and quality assessment (QA) programs were established and maintained to identify failures in quality as they occur from 09/23 /2022 to the date of the survey. Findings Include: 1. On the day of the survey, 09/19 /2023 at 12:13 pm, the laboratory could not provide documentation of the QA activities performed to assure the quality of laboratory (preanalytical, analytical, and

	postanalytical) services from 09/23/2022 to 09/19/2023. 2. Further review of the laboratory's QC records revealed that corrective actions were not documented for 1 of 31 days in July 2023 when QC failures occurred on the Abbot iSTAT analyzer. -Level 3 QC for the Chem 8+ testing stated failed with no corrective action documented on 07 /09/2023. 3. TC #2 confirmed the findings above on 09/19/2023 at 02:00 pm.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's i-STAT Critical Skill Evaluation Form and interview with technical consultant #2 (TC), the TC failed to evaluate and document the competency of 42 of 42 testing personnel (TP) through internal blind testing or external proficiency testing (PT) samples for hematology and chemistry testing performed from 09/22/2022 to the date of the survey. Findings include: 1. On the day of the survey, 09/19/2023 at 12:54 pm, review of the i-STAT Critical Skill Evaluation Form revealed the technical consultant failed to evaluate and document the test performance of 42 of 42 testing personnel through internal blind sampling, external proficiency testing or previously analyzed samples for the following from 09/22/2022 to 09/19/2023: -Abbot i-STAT Chem 8+ cartridges: hematocrit, sodium, potassium, chloride, glucose, creatinine, urea, total carbon dioxide (CO2), and ionized calcium. 2. The laboratory performed 712 hematology examinations and 5,696 chemistry examinations in 2022 (CMS-116 annual volume). 3. TC #2 confirmed the finding above on 09/19/2023 at 02:00 pm.