| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 52D2193939 | 03/14/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Froedtert Community Hospital - Pewaukee | 209 Pewaukee Road, Pewaukee, WI | |

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 |
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| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records from the 2022 Chemistry Core events and interview with the technical consultant, the laboratory did not document review of D-dimer results that the PT provider did not grade in two of two events performed with the Pathfast analyzer. Findings include: 1. Review of API (American Proficiency Institute) PT records for the Chemistry core events in 2022 showed the laboratory used the Pathfast analyzer for D-dimer testing in the second and third events. The records showed the PT provider did not grade the D-dimer results for samples CM-08 and CM-09 in the second event and samples CM-11 and CM-12 in the third event. The laboratory reported the D-dimer concentration for each of these samples as >5 ugFEU/mL (greater than 5 microgram Fibrinogen Equivalent Units / milliliter). The records showed no documented review of the ungraded results. 2. Interview with the technical consultant on March 14, 2023 at 10:50 AM confirmed the laboratory did not document the review of the unscored D-dimer PT results. |
| **D5409** | PROCEDURE MANUAL<br>CFR(s): 493.1251(e)<br><br>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory procedures and interview with the technical consultant, the laboratory did not maintain one of one discontinued procedure with the date the test was discontinued and one of one new procedure with the initiation date of testing at this laboratory. Findings include: 1. Interview with the technical consultant on March 14, 2023 at 12:30 PM confirmed the laboratory's use of the Triage test system was discontinued on April 11, 2022 and replaced with the Fastpath test system. 2. Review of the printed procedure manual showed no procedure for the Triage test system. The procedure for the Fastpath system showed the origination date for the procedure was January 1, 2022. The procedure did not include an initiation date for use in this laboratory. 3. Review of the electronic version of the Triage test system procedure showed no date of discontinuation for the test system at this laboratory. 4. Further interview with the technical consultant on March 14, 2023 at 12: 30 PM confirmed the laboratory had removed the Triage procedure from the manual without documenting the date of discontinuation and confirmed the Fastpath procedure did not show the initiation date for testing at this laboratory. |
| **D5545** | HEMATOLOGY<br>CFR(s): 493.1269(b)(d)<br><br>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and procedures, and interview with the laboratory director, the laboratory has not performed two levels of quality control (QC) each eight hours of patient testing in twelve of twelve months since starting D-dimer testing on the Fastpath analyzer in April 2022. Findings include: 1. Review of Pathfast worksheets showed QC testing was performed once per day for the three tests performed on the test system. 2. Review of the 'Pathfast Instrument Testing (Troponin I, NT-pro-BNP, D-dimer)' procedure showed the procedure required two levels of external QC daily for D-dimer testing. The procedure did not include instructions to perform QC testing every eight hours of patient testing. 3. Interview with the laboratory director on March 14, 2023 at 11:50 AM confirmed the laboratory did not perform QC testing each eight hours of patient testing on the Fastpath D-dimer test since starting testing in April 2022. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br><br>This STANDARD is not met as evidenced by: |

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| | Based on surveyor review of test records and interview with the laboratory director, the laboratory did not maintain a record system that identified which testing person performed each complete blood count (CBC) analysis on the Sysmex XN-330 hematology analyzer in 2022 and 2023. Findings include: 1. Review of test records showed no paper records of CBC tests performed on the Sysmex XN-330 hematology analyzer. Review of electronic records in the medical record showed no record of which person performed the CBC tests on the Sysmex XN-330. The laboratory estimated they performed 2583 CBCs annually. 2. Interview with the laboratory director on March 14, 2023 at 1:25 PM confirmed the laboratory did not maintain a record system that included the identity of the testing personnel who performed CBC testing on the Sysmex XN-330 analyzer. |
| **D6019** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iv)<br><br>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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records and interview with the technical consultant, the laboratory director did not ensure the laboratory developed and followed a corrective action plan when the pO2 (Oxygen partial pressure) result for one of four graded pO2 results in event three in 2022 was unacceptable after the laboratory had an unacceptable pO2 result in event two. Findings include: 1. Review of the API (American Proficiency Institute) PT report for the 2022 Chemistry - Core third event showed the laboratory received an unacceptable grade for pO2 on sample IB-14. The record also showed sample IB-12 was ungraded due to a lab reported test problem. The record included no evidence the laboratory reviewed the unacceptable result. Review of the API Chemistry Core 'Performance Summary' showed the laboratory received an 80% score for pO2 on the second and third events in 2022. 2. Interview with the technical consultant on March 14, 2023 at 10:15 AM confirmed the laboratory did not document review of the unacceptable pO2 result and an approved corrective action plan was not developed or followed. |
| **D6072** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1425(b)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of procedures and quality control (QC) records and interview with the technical consultant, testing personnel did not document external QC twice daily for the Sysmex XN-330 fourteen of thirty-one days in December 2022. Findings include: 1. Review of the procedure 'Sysmex 330XN-L for Complete Blood Counts (CBC) with 6 Parameter Differentials' showed performance of three |

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| | levels of QC material will be tested two times a day. 2. Review of QC records on the Sysmex maintenance logs for December 2022 showed personnel did not document control testing during the evening shifts on December 5, 13, 15, 16, 17, 18, 19, 21, 22, 25, 27, 28, 30, and 31. 3. Interview with the technical consultant on March 14, 2023 at 1:00 PM confirmed testing personnel did not adhere to the laboratory's quality control policies when they did not perform external QC twice daily on fourteen days in December 2022. |