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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2061866 | (X3) Date Survey Completed 08/24/2023 |
| Name of Provider or Supplier Patient First - East Norriton | Street Address, City, State 400 East Germantown Pike, East Norriton, 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 |
|---------------------------|---|
| D3009 | <p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor (TC) #1, the laboratory failed to ensure a general supervisor (GS) who met the state requirement was on the laboratory premises during all hours in which tests were performed from 08 /17/2021 through the day of survey. Findings include 1) The PA regulations (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, 08/24/2023 at 01:20 pm., a review of Laboratory Personnel Report (Pennsylvania State), personnel credentials and personnel schedules for 3 of 3 months (Dec 2021, April 2022, and August 2022) requested during the survey revealed that the laboratory failed to ensure a qualified GS was on site every hour of patient testing as required per the state regulations. 3) The laboratory failed to provide personnel schedules for February 2023 and June 2023 requested during the survey. 4) On 08/24/2023 TC#1 confirmed the above findings around 02:00 pm.</p> |
| D6019 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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</p> |

when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with Technical Consultant (TC)#1, the laboratory director failed to ensure that the approved corrective action established for incorrect PT results was followed for 1 of 2 AAB-MLE PT events in 2023. Finding include: 1. On the day of survey, 08/24/2023 at 10:30 am, review of the AAB-MLE PT records revealed that the laboratory received a 80 % score for Basophil % for the Non-Chemistry M1 2023 event. 2. The AAB-MLE FAQs sheet states " * is an out of range or incorrect response. This means corrective action is required on your part." 3. The laboratory's AAB-MLE PT corrective action records for the Non-Chemistry M1 2023 event stated, "will have an additional person review results as well going forward." 4. The laboratory failed to provide documentation for the additional person that reviewed results before submission to AAB-MLE for Non-Chemistry M2 2023. 5. TC#1 confirmed the findings above on 08/24/2023 around 02:00 pm.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (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.

This STANDARD is not met as evidenced by:

Based on record review and interview with the technical consultant (TC)#1, the technical consultant failed to evaluate the competency assessment for 5 of 8 testing personnel (TP) performed testing in moderate complexity testing in microbiology, clinical chemistry, hematology and urinalysis from 08/17/2021 to the day of survey. Findings include: 1. On the day of survey 08/24/2023 at 01:20 pm, review of the CMS 209, personnel schedules and competency assessment records revealed that the Technical Consultant did not evaluate the annual competency assessment for 3 of 8 TP (CMS 209 personnel #10, #11, and #12) who performed moderate complexity testing in microbiology, clinical chemistry, hematology and microscopic urinalysis in December 2021, April 2022 and August 2022. 2. The laboratory failed to provide personnel schedules for February 2023 and June 2023 requested during the survey. 3. The following competency assessments were incomplete for 2 of 8 TP (CMS 209 personnel #4, and #8): - The competency assessment for Personnel #4 performed in march 2022 (potassium hydroxide, Wet mounts, pin worm and fecal) did not include the following points: - Point 1 Direct observations of routine patient test performance - Point 2 Monitoring the recording and reporting of test results - Point 3 Review of intermediate test results, quality control, proficiency testing and preventive maintenance. - Point 4 Direct observation of performance of instrument maintenance and function checks. - The competency assessment for Personnel #8 for urinalysis performed in March, 2023 did not include: - Point #2: Monitoring the recording and reporting of test results. 4. The TC#1 confirmed the findings above on 08/24/2023 around 02:00 pm.