| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 44D0313875 | 11/30/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Saint Francis Medical Partners East, Llc | 4066 Summer Avenue, Memphis, TN | |

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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| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's quality control (QC) and quality assessment records, and interview with the technical consultant, the laboratory failed to correct identified problems with QC lot management for six of nine QC lots reviewed in 2019 and 2020. The findings include: 1. Review of the laboratory's QC and quality assessment records revealed the following: Review done 8.7.19 for July 2019 QC records-noted problems with overlap in QC lots. No corrective action done. Review done 10.8.20 for September 2020 QC records-noted problems with overlap in QC lots. No corrective action done. 2. Interview with the technical consultant on 11.23.2020 at 10:45 am confirmed the laboratory's quality assessment identified problems with management of QC files in 2019 and 2020 with no corrective action performed. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of laboratory records and interview with the technical consultant the laboratory failed to define acceptable temperatures for refrigerated storage of complete blood count (CBC) quality controls (QC) and room temperature in 2019 and 2020. The findings include: 1. Review of the laboratory's temperature records for the refrigerator used for storing CBC quality controls and recording room temperature revealed that all temperatures were recorded in Celsius degrees from May 2019 through September 24, 2020. The temperature log did not define the acceptable temperature ranges for recording in Celsius. 2. Interview with the technical consultant on November 23, 2020 at 11:10 am confirmed the laboratory failed to define the Celsius temperature range for the CBC QC storage refrigerator and room temperature in 2019 and 2020. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) Form CMS-209 (CMS 209), review of testing personnel records, and interview with the office manager and technical consultant, the laboratory director failed to ensure testing personnel number five had documentation of appropriate education prior to testing patient specimens in 2019 and 2020. The findings include: 1. Review of the CMS 209 revealed the name of testing personnel number five listed as performing moderately complex testing. 2. Review of testing personnel records revealed no documents were present that verified level of education. Initial competency was completed on 12.13.2019. 3. Interview with the office manager and technical consultant on November 30, 2020 at 8:40 am confirmed testing personnel number five performs patient testing for moderately complex complete blood count. The laboratory director failed to ensure testing personnel number five had appropriate education for performing moderately complex testing in 2019 and 2020. |