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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D1083507 | (X3) Date Survey Completed 10/09/2024 |
| Name of Provider or Supplier Jfk Medical Center Satellite Emergency | Street Address, City, State 1200 Randolph Road, Plainfield, NJ | |
| 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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| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), and interview with the General Supervisor (GS), the laboratory failed to have a procedure for a bi-annual method comparison between i-Stat analyzers for Routine Chemistry from 10/6/22 to the date of survey. The GS confirmed on 10/9/24 at 12:30 pm that the laboratory failed to have the above mentioned procedure. b) Based on surveyor review of the PM and interview with the GS, the laboratory failed to have a complete Quality Control Verification (QVC) procedures for Hematology testing from 10/6/22 to the date of survey. The findings include: 1) The procedure "G. new Lot crossover or parallel studies" does not specify the the amount of times the Quality Control (QC) material is to be run before being put into use. 2) The procedure "G. new Lot crossover or parallel studies" does no have procedure to compare QVC results with the values on the Manufactures assay sheet. 3) The GS confirmed on 10/9/24 at 12:30 pm that the laboratory failed to follow the have the aforementioned procedures.</p> |
| D5445 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through</p> |

493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the lack of an Individualized Quality Control Plan (IQCP) and interview with the General Supervisor (GS) the Laboratory failed to have an approved Risk Assessment (RA), Quality Control Plan (QCP) and Quality Assessment (QA) plan for Routine Chemistry performed on the i-Stat and Alere Triage analyzers from 10/6/22 to the date of survey. The findings include: 1) The GS stated the laboratory followed the IQCP plan for Routine Chemistry performed on the i-Stat and Alere Triage analyzers. 2) There was no documented evidence that an IQCP was completed for Routine Chemistry performed on the i-Stat and Alere Triage analyzers 3) The GS confirmed on 10/9/24 at 11:00 am the laboratory failed to have an approved Quality Control Plan (QCP) for Routine Chemistry.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the lack of Quality Control Verification (QCV) records and interview with the General Supervisor (GS), the laboratory failed to verify QC material before use for routine chemistry and Hematology tests performed on the Sysmex XN-430, i-Stat, and Alere Triage from 10/6/2022 to the date of survey. The findings include: 1) There was no documented evidence that QCV was performed on the aforementioned analyzers. 2) The GS confirmed 10/9/2024 at 1:15 pm there was no documented evidence that QC material was verified before putting in use.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

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| | <p>Based on the lack of laboratory's Individualized Quality Control Plan (IQCP) and interview with the General Supervisor (GS) the laboratory failed to have documentation of data used to support their Risk Assessment (RA) for testing on the Stat and Alere Triage before reporting patient results from 10/6/22 to the date of the survey. The GS confirmed at 12:30 PM on 10/9/24 the laboratory did not have documentation of controls used to support their RA.</p> |
| <p>D5791</p> | <p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with General Supervisor (GS) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 10/6/22 to the date of survey. The findings include: 1. The Laboratory failed to have a Corrective Action (CA) procedure for Quality Control (QC). 2. The Laboratory failed to have a Quality Control Verification (QCV) procedure for routine chemistry on the i-Stat, and Alere Triage analyzers. 3. The GS confirmed on 10/9/24 at 11:45 am that the laboratory failed to have CA and QVC procedures for QC.</p> |
| <p>D6013</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS) the Laboratory Director (LD) failed to ensure that PS procedures performed for Hematology testing performed on the Sysmex XN-430 analyzer were adequate from February 2023 to the date of survey. The findings include: 1. There was no documented evidence that a normal patient range study was performed prior to the start of patient testing. 2. The GS confirmed on 10/9/2024 at 11:15 am that PS records were not adequate.</p> |
| <p>D6021</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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</p> |

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on the surveyor review of the Procedure Manual and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to establish a complete Quality Control (QC) plan from 4/19/23 to the date of the survey. The findings include: 1) The QC procedure did not define the which Sysmex BeyondCare Quality Monitor (BCQM) reports to be generated and reviewed. 3) The QC procedure did not define the frequency in which to review BCQM reports. 4) The QC procedure did not define parameters for acceptable QC results. 5) There was no documented evidence that an Individualized Quality Control Plan (IQCP) was developed for Routine Chemistry performed on the i-Stat and Alere Triage analyzers. 6) The QC procedure did not specify who will review QC. 7) The GS confirmed on 10/9/24 at 11:00 am that the LD failed to establish a complete QC program.