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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>25D1001137      | <b>(X3) Date Survey Completed</b><br><br>12/17/2019 |
| <b>Name of Provider or Supplier</b><br><br>Jones Family Medicine Clinic Pllc   | <b>Street Address, City, State</b><br><br>30 Circle J Drive Suite 1, Laurel, MS |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5401</b>              | <p>PROCEDURE MANUAL<br/>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:<br/>Based on review of quality control (QC) records for CK-MB and Troponin I testing on the Alere Triage Meter Pro from 4-17-19 through 11-1-19, the laboratory's Individualized Quality Control Plan (IQCP), instruments printouts of patient results, and confirmation by the technical consultant on 12-17-19 at 4:30 p.m., the laboratory failed to follow its IQCP for performing two levels of external quality control at least every thirty days and with each new lot or shipment of test cartridges, when a total of twenty-seven patients were tested for CK-MB and Troponin I. Findings include: Review of the laboratory's IQCP and interview with the technical consultant on 12-17-19 at 4:30 p.m. revealed the laboratory's IQCP states that external controls for CK-MB and Troponin I testing on the Alere Triage Meter Pro will be performed at least every thirty days and with each new lot or shipment of test cartridges. Review of QC records for CK-MB and Troponin I testing on the Alere Triage Meter Pro from 4-17-19 through 11-1-19 revealed external controls for CK-MB and Troponin I testing were not documented, as performed, from 6-17-19 until 11-1-19. The following patients were tested for CK-MB and Troponin I on the Alere Triage Meter Pro from 7-20-19 through 9-19-19, without external controls performed in the previous 30 days: 7-20-19--Patients #26737, #2495. 7-21-19--Patient #10817. 7-27-19--Patient #7719. 7-30-19--Patient #20087. 8-3-19--Patient #14207. 8-4-19--Patient #63446. 8-5-19--Patient #13007. 8-6-19--Patient #2359. 8-7-19--Patient #6700. 8-9-19--Patient #58334. 8-10-19--Patient #6989. 8-15-19--Patient #14494. 8-22-19--Patient #13836. 8-23-19--Patient #16483. 8-26-19--Patient #12908, #53821. 8-30-19--Patient #40664, #12977.</p> |

8-31-19--Patient #59298. 9-1-19--Patient #10854. 9-5-19--Patient #25445. 9-6-19--Patient #46660. 9-7-19--Patient #64510. 9-9-19--Patient #43270. 9-11-19--Patient #2562. 9-19-19--Patient #14679.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of the TOSOH AIA-Pack PSA (prostate specific antigen) reagent test pack in the laboratory refrigerator on 12-17-19 at 10:15 a.m. and review of instrument printouts for the TOSOH AIA-360 analyzer from 12-1-19 through 12-16-19, the PSA reagent test pack, Lot #12128A9, was used for PSA testing on twenty-seven patient specimens after it had exceeded its expiration date of 11-30-19. Findings include: Observation of the TOSOH AIA-Pack PSA reagent test pack, Lot #12128A9, in the laboratory refrigerator on 12-17-19 at 10:15 a.m. revealed the manufacturer's expiration date for the test pack was 11-30-19. Review of instrument printouts of patient test results for the TOSOH AIA-360 analyzer from 12-1-19 through 12-16-19 revealed the PSA reagent test pack, Lot #12128A9, was used for testing on the following patient specimens for six days after it had exceeded its expiration date of 11-30-19: 12-4-19--Patient #1032075, #1032076, #1032077, #1031980. 12-6-19--Patient #1032117, #1032118, #1031962, #1032019, #1032116. 12-9-19--Patient #1032172, #1032173, #1032174, #1032099, #1032130, #1032097. 12-11-19--Patient #1032234, #1032235, #1032236, #1032201. 12-13-19--Patient #1032342, #1032343, #1032344. 12-16-19--Patient #1032435, #1032436, #1032437, #1032422, #1032423.

**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 review of calibration verification records for the TOSOH AIA-360 analyzer since the last survey on 12-19-17 and confirmation by the technical consultant, the laboratory failed to document, as performed, calibration verification for T3 Uptake testing at least once every six months since 11-12-18. Findings include: Review of calibration verification records for the TOSOH AIA-360 analyzer since the last survey on 12-19-17 revealed no documentation of calibration verification performed for T3 Uptake testing since 11-12-18. The technical consultant confirmed T3 Uptake calibration verification had not been performed since 11-12-18.

**D6072**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(3)

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.

This STANDARD is not met as evidenced by:  
Based on review of quality control (QC) records for CK-MB and Troponin I testing on the Alere Triage Meter Pro from 4-17-19 through 11-1-19, the laboratory's Individualized Quality Control Plan (IQCP), instruments printouts of patient results, and confirmation by the technical consultant on 12-17-19 at 4:30 p.m., testing personnel, responsible for moderate complexity testing, failed to follow the laboratory's IQCP for performing two levels of external quality control at least every thirty days and with each new lot or shipment of test cartridges, when a total of twenty-seven patients were tested for CK-MB and Troponin I from 7-20-19 through 9-19-19. Refer to D5401 (Failure to follow IQCP for CK-MB and Troponin I testing).