

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0468385	<b>(X3) Date Survey Completed</b> 05/01/2019
<b>Name of Provider or Supplier</b> Mcclintock Family Medicine	<b>Street Address, City, State</b> 306 North Chestnut Street, Harrison, AR	
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>
<b>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Through a review of logs titled "Frend (TSH/PSA) QC" for September 2018 through March 2019, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions when results of PSA quality controls were not acceptable. Survey findings include: A. On 10/14/2018 (one of five days of quality control testing in October 2018), the PSA Level 1 Control was run four times before an acceptable result was reported. There is no documentation of corrective actions performed to achieve an acceptable result on the fourth run. The acceptable range in use for PSA Level 1 Control on 10/14/2018 was 0.87 to 1.07. The results reported were 0.86, 0.83, 1.21, and 1.05. B. On 3/1/2019 (one of two days of quality control testing in March 2019), the PSA Level 2 Control was run five times before an acceptable result was reported. There is no documentation of corrective actions taken for the unacceptable control. The acceptable range in use for PSA Level 2 Control on 3/1/2019 was 9.66 to 14.46. The results reported were 14.47, 15.10, 14.74, 15.36, and 12.66. C. In an interview at 10:59 on 5/1/2019, the technical consultant (as listed on the form CMS-209) confirmed there was no documentation of corrective actions for the unacceptable quality controls.</p>
<b>D5785</b>	<b>CORRECTIVE ACTIONS</b>

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Through a review of the Cliniqa Liquid QC Immunoassay Control package insert, a review of the laboratory temperature logs for 2018 and 2019, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions taken when freezer temperatures were outside of the acceptable criteria. Survey findings include: A. The Cliniqa Liquid QC Immunoassay Control package insert states that the control is stable until the expiration date on the vial if it is stored unopened at less than or equal to -20 degrees Celsius. B. During a review of temperature records for 2018 and 2019 it was determined that temperatures were documented warmer than -20 degrees on 7 of 23 days in October 2018, 8 of 20 days in November 2018, 7 of 19 days in December 2018, 7 of 22 days in January 2019, 9 of 20 days in February 2019, and 4 of 21 days in March 2019. Although there is a column on the form to document actions taken to get the temperature within acceptable limits there were no actions documented on any of the days when temperatures were unacceptable. C. In an interview at 11:15 on 5/1/2019, laboratory employee #3 (as listed on the form CMS-209) stated the unacceptable temperatures were due to the freezer defrost cycle [which the laboratory has not taken steps to correct].