

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2121560	(X3) Date Survey Completed 02/06/2019
Name of Provider or Supplier Arkansas Pathology Associates Histology Hot Spgs	Street Address, City, State 300 Werner St, Hot Springs, AR	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the Histopathology temperature records for 2018 and 2019, lack of documentation, as well as interviews with histopathology laboratory staff it was determined the laboratory failed to document corrective actions when humidity and temperatures of the embedding center paraffin dispenser did not meet the laboratory criteria for acceptability. As evidenced by: A. A review of the 2018 records (twelve of twelve months) for humidity revealed the laboratory's humidity range as 30-70%. A further review revealed the humidity was out of range in January 2018 for twenty-one of twenty-one days; February 2018, seven of twenty days; March 2018, eight of twenty-one days; April 2018, four of twenty-two days; November 2018, fourteen of twenty-one days and December 2018, ten of twenty days. The laboratory failed to documented corrective actions when Humidity conditions were outside the laboratory's acceptable range. B. A review of temperature records for 2018 and 2019 revealed the embedding center temperature for the paraffin dispenser as 61 +/- 3 degrees Celsius (58 to 64 Degrees Celsius). A review of temperature records for twelve of twelve months revealed the paraffin dispenser temperatures were outside of the laboratory range for acceptability in April 2018, two of twenty-three days; in May</p>

2018, one of twenty-two days and December 2018, seventeen of twenty-days. In January 2019, twenty of twenty-two days. The laboratory failed to document corrective actions on days when paraffin dispenser temperatures were outside of the laboratory's acceptable range. C In an interview at 10:46 a.m. on 2/6/2019 the technical consultant confirmed the temperatures and humidity listed above were outside of the acceptable ranges and the laboratory had no documentation of corrective action.