

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2006249	<b>(X3) Date Survey Completed</b> 07/03/2019
<b>Name of Provider or Supplier</b> Family Medicine Of White Hall	<b>Street Address, City, State</b> 7245 Sheridan Rd, White Hall, 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>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by:                      . Through a review of the laboratory Policy and Procedure Manual, observations made during a tour of the laboratory, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to follow written policies for positive identification of urine specimens. As evidenced by: A. A review of the laboratory policy for specimen labeling revealed "All specimens are labeled to assure optimum integrity of the specimen through all phases of testing. The label is to include patient's full name and other unique identifier. (Date of birth, chart number or accession number.) " B. During a tour of the laboratory, at 1349 on 7/2/2019, the surveyor observed fifteen urine containers in the laboratory sink. Three of fifteen urine containers were labeled with the patients first and last name only. C. In an interview at 1349 on 7/2/2019, laboratory personnel #3 (as listed on form CMS 209) confirmed the urine containers were not labeled according to laboratory policy.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:

. Through a review of the TOSOH AIA-360 instrument manual, maintenance records for 2019, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to document maintenance with at least the frequency specified by the manufacturer. As evidenced by: A. The laboratory utilizes the Bioscience TOSOH AIA-360 Immunoassay analyzer to process Free Thyroxine (FT4), Total Triiodothyronine (TT3), Thyroid Stimulating Hormone (TSH), Prostate Specific Antigen (PSA) and Testosterone. B. A review of the Bioscience TOSOH instrument manual revealed the six month maintenance for the TOSOH Immunoassay analyzer: "Replace filters for diluent and wash bottles." C. A review of the TOSOH AIA-360 maintenance schedule for 2018 (twelve of twelve months) and 2019 (six of six months) revealed the six month maintenance was performed in January and June of 2018 and June of 2019 (three of four times due). Maintenance was not performed in January of 2019. D. In an interview on 7/3/2019 at 0930, laboratory personnel # 4 (as listed on CMS form 209) confirmed the lack of documented six-month maintenance for the TOSOH Immunoassay analyzer.