

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468338	(X3) Date Survey Completed 04/16/2021
Name of Provider or Supplier Baxter Health Fulton County Hospital	Street Address, City, State 679 N Main St, Salem, 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
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Through lack of documentation and interview it was determined that the laboratory failed to provide written instructions for specimen collection and handling for clients who submit specimens to the laboratory. Findings follow: A. In an interview on 04/16/21 at 0900 AM the laboratory staff member, identified as number two on the CMS 209 form, said that the laboratory accepted specimens from three home health agencies and requested tests included CBC's, Urine Cultures, Prothrombin Times, CMP's and A1C Hemoglobin and the specimens were transported by agency personnel. B. Upon request, the laboratory could not produce a specimen collection, handling and transportation manual that it supplied to the laboratory's clients. C. In an interview on 4/16/21 at 0900 AM, the laboratory staff member identified as number two on the CMS 209 form, confirmed that the laboratory failed to provide a specimen collection and handling manual to the laboratory's clients.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:
Through observation and interview with laboratory staff it was determined that the laboratory failed to label the contents of one of one containers of deionized water. findings follow: A) During a tour of the laboratory on 4/16/21 at 01:15 PM a plastic container containing a liquid substance was observed on the counter labeled as only "4 /15". B) When asked during an interview on 4/16/21 at 01:15 PM what the identity of the contents of the container were, the laboratory staff member, identified as number two on the CMS 209 form, said the container held deionized water and the container was not labeled as to contents.

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:
Through observation and interview it was determined that one of one KOH solution used to perform KOH microscopic preparations was expired in the laboratory microscopy area. Findings follow: A) During a tour of the laboratory on 4/16/21 at 01; 15 PM one of one bottles of MCG KOH, lot # 8506-01 expiration date 2020-07-31, was observed in the cabinet in the laboratory microscopy area. B) In an interview on 04/16/21 at 01:15 PM the laboratory staff member, identified as number two on the CMS 209 form, said that the bottle of KOH solution identified above had exceeded its expiration date and was available for use.