

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0686032	<b>(X3) Date Survey Completed</b>  02/06/2019
<b>Name of Provider or Supplier</b>  Jackson Hospital & Clinic	<b>Street Address, City, State</b>  4154 Carmichael Road, Montgomery, AL	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's test menu with the testing personnel, a review of CAP (College of American Pathologists) proficiency testing records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to enroll in proficiency testing to the extent of patient testing in the Microbiology specialty. This affected the survey period of the last quarter of 2016, 2017 and 2018. The surveyor reviewed twenty CAP proficiency testing evaluations. The findings include: 1. During the initial tour of the laboratory, TP #1 identified the specialties and testing done at the laboratory. When discussing the Microbiology specialty, TP #1 stated the laboratory performed "other cultures", in addition to urine and throat cultures, which were reported as growth or no-growth by the laboratory personnel (the physicians). The surveyor asked TP #1 to describe "other cultures." TP #1 stated the physicians sometimes requested cultures, such as of ear drainage, an abscess, the skin (sore or lesion), or possibly from the rectum. TP #1 further explained the testing personnel would inoculate these specimens on a sheep blood plate, and the physician would determine if there was growth. If growth occurred, the laboratory would send the sample out for identification and sensitivity. At this time, the volume counts for the tests (as listed on the CMS form #116) were discussed. TP #1 indicated the</p>

laboratory performed about thirty-two (32) "other cultures" in 2018. TP #1 also confirmed these tests were billed through insurance. 2. The CAP proficiency testing records for 2017 and 2018 did not include any proficiency testing for cultures beyond urine and throat cultures. 3. In an interview on 2/06/2019 at 1:35 PM, TP #1 confirmed again the volume of these "other cultures" as stated in paragraph one. TP #1 also stated the laboratory has been performing this testing for many years and has not changed its processes. TP #1 also confirmed the laboratory was not performing any proficiency testing for cultures of the above mentioned specimen types, other than urine and possible microbial agents of the throat.

**D6088**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's test menu with the testing personnel, a review of CAP (College of American Pathologists) proficiency testing records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory director failed to ensure the laboratory enrolled in proficiency testing to the extent of patient testing in the Microbiology specialty. This affected the survey period of the last quarter of 2016, 2017 and 2018. The surveyor reviewed twenty CAP proficiency testing evaluations. The findings include: 1. Refer to D2000 (493.801) Enrollment and Testing of Samples.