

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0707800	(X3) Date Survey Completed 06/17/2021
Name of Provider or Supplier American Health S Llc DbA American Health	Street Address, City, State 15712 Sw 41 St Suite 16, Davie, FL	
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
D0000	An unannounced complaint survey for 2021007526, was conducted on 6/16/2021 to 6/17/2021 at American Health Associates. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to have a biological specimen refrigerator in the drawing room to ensure urine specimens are not placed in a refrigerator used for employee food storage. Findings included: An observation of drawing station on 6/16/2021 at 9:00 AM revealed that the room had one refrigerator. The refrigerator had ice buildup and was used to store food inside and was not labeled for biological specimen use. A review of Urine Culture procedure stated "transportation of urine to the laboratory after or if collection cannot not be deliver to the laboratory within 2 hours after of collection refrigerate up to 24 hrs. If the urine culture tube is used, the urine specimen is viable for culture up to 72 hours." During an interview on 6/16/2021 at 9:30 AM, the drawing station technician confirmed there was only one unlabeled refrigerator in the room. They stated a courier picks up only stat samples and the other courier picks specimen up after 5 PM to deliver to the laboratory daily.</p>
D5201	<p>CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231</p> <p>The laboratory must ensure confidentiality of patient information throughout all</p>

phases of the total testing process that are under the laboratory's control.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to ensure the privacy of patient records in the drawing room. Findings included: An observation of drawing station on 6/16/2021 at 9:30 AM displayed a stack of patient's requisitions in a box with names, addresses, birth dates and social security numbers were kept in a corner by an opened door by the waiting room. The open door is the only entrance into the drawing station from the waiting room. Review of General Overview of Health Insurance Portability and Accountability Act (HIPPA) revealed "Any facility with a patient service center have designated patient entrances that are locked and unlocked during normal operating hours by authorized employee. The patients are escorted to and from the drawing room by phlebotomist." During an interview on 6/16/2021 at 9:30 AM with the drawing technician, they confirmed the stack of patient information in a box by the door that led to the waiting room.

D5205

COMPLAINT INVESTIGATIONS

CFR(s): 493.1233

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have a written policy for complaints in the laboratory. The laboratory failed to document the canceled urine specimen sent to reference laboratory in a complaint log. Findings included: Review of patient urine records displayed a urine specimen collection issue with a canceled urine test from a reference laboratory in 4/08/2021. Review of general laboratory procedure revealed no written policy for complaints made in the laboratory. Review of complaint log revealed no written documentation for urine test canceled on 4/08/2021 from reference laboratory. During an interview on 6/17/2021 at 5:26 PM, the owner and laboratory consultant confirmed no written complaint policy and documentation of canceled urine test from a reference laboratory.

D5393

PREANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1249(b)(c)

The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to follow their lab requisition policy and document urine specimens in requisition logs from April 1, 2021 to June 17, 2021. Findings included: Review of lab requisition and lab log policy revealed "Nursing staff is required to include specific information on the requisition prior to blood specimen being collected. Requisitions are kept in lab log on each unit

of the nursing facility and completed requisition must accompany all specimen submitted for testing. The laboratory requires that nursing staff complete a lab log sheet that lists each patient's name room number date and tests ordered. Phlebotomists are required to ensure that requisitions are completed with appropriate information and that each requisition corresponds to match entry on the lab log." Review of Hillsboro Lab Log revealed no written list of urine specimens document on log sheets from April 1, 2021 to June 17, 2021. During an interview on 6/17/2021 at 5:28 PM, the owner and laboratory consultant confirmed the laboratory failed to follow their lab requisition policy and document urine specimen in requisition logs.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to have a post analytic quality assurance (QA) policy for urine specimen sent out to reference laboratories to ensure patients received their test results. Findings Included: Review of Patient 27073230 urine test results revealed on 4/8/2021 urine test was canceled due to insufficient collection of sample. On 5/15/2021 patient's urine sample was received and tested with a final report. Review of Laboratory Computer Record System displayed that patient 27073230 was canceled for urine tests on 4/8/2021 and 5/15/2021 with no documentation for cancellation of urine test. A review of QA record revealed there was no written post analytic QA policy for reviewing patient test results from specimen sent out to another laboratory for testing. There was no written documentation to indicate if the patient receive information for urine test results sent out to reference laboratories. During an interview on 6/17/2021 at 5:30 PM, the owner and laboratory consultant confirmed the laboratory failed to have a post analytical QA policy for urine specimen sent out to reference laboratories to ensure patients received their test results