

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2108980	(X3) Date Survey Completed 03/30/2023
Name of Provider or Supplier Bhg Reference Lab, Llc	Street Address, City, State 1734 Madison Ave, Suite B, Memphis, TN	
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	A recertification survey was conducted on 03/30/23. The facility was found to be NOT in compliance with the following 42 CFR Part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed: 493.1240 Pre-Analytic Systems
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel records, proficiency testing records and interview with the general supervisor, the laboratory failed to ensure proficiency testing (PT) was performed by all testing persons in 2021, 2022, and 2023. The findings include: 1. Review of testing personnel records revealed two testing personnel performed urine drug screen testing in the laboratory in 2021, 2022, and 2023. 2. Review of the laboratory's proficiency testing records revealed that five of seven PT events were performed by the previous general supervisor (2021 events one, two, and three; 2022 events one and three). 3. Interview with the current general supervisor on 03/30/23 at 3:45 p.m. confirmed that there were two testing personnel who performed urine drug screen testing in the laboratory in 2021, 2022 and 2023 and that the previous general supervisor performed five of seven PT events during that period.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's alternative quality assessment records, and interview with the quality manager, the laboratory failed to ensure results for three of six quantitative urine ethanol test events from 2021 and 2022 had been reviewed or evaluated to determine the laboratory's accuracy. The findings include: 1. Review of the laboratory's alternative quality assessment records for the quantitative urine ethanol analyte revealed no review of the results for 2021 event two, 2022 event one, and 2022 event two. 2. Interview with the quality manager on 04/03/23 at 2:45 p.m. confirmed the laboratory failed to ensure the results of the alternative quality assessments used for verifying the accuracy of the quantitative urine ethanol analyte had been reviewed for three of six test events in 2021 and 2022.

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on observation of the laboratory, review of the laboratory procedure manual, review of the laboratory's initial performance establishment studies for specimen stability, randomly selected final patient test reports and staff interviews, the laboratory failed to establish policies and procedures for specimen storage, preservation, and conditions for transportation (Refer to D5311) and failed to have an effective assurance process in place to prevent errors in test performance outside the laboratory's established specimen stability ranges (Refer to D5393).

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the laboratory procedure manual, and staff interviews, the laboratory failed to establish policies and procedures for specimen storage, preservation, or conditions for transportation on the date of the survey (03/30/23). The findings include: 1. Observation of the laboratory on 03/30/23 at 10:15 a.m. revealed three instruments (Synermed IR 500 (x2) and Synermed IR 1200) in use for performing patient testing on urine for the following analytes: qualitative assays for amphetamine, barbiturate, benzodiazepine, buprenorphine,

cocaine, fentanyl, methadone, methadone metabolite, opiates, oxycodone, phencyclidine, cannabinoids, quantitative urine ethanol, urine creatinine, and urine pH. 2. Review of the laboratory's procedure manuals revealed the laboratory did not have specific procedures for specimen storage, preservation, or conditions for transportation. 3. Interview with the laboratory supervisor on 03/30/23 at 3:45 p.m. and virtual interview with the quality manager on 04/03/23 at 2:45 p.m. confirmed the laboratory did not have procedures for storage, preservation or transportation in 2023.

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 observation of the laboratory, review of the laboratory's initial performance establishment studies, randomly selected final patient test reports, and staff interview, the laboratory failed to have an effective quality assessment process in place to prevent errors with performance of patient testing outside the laboratory's established specimen stability range in 2021, 2022, and 2023 for qualitative urine drug screen, quantitative urine ethanol, urine creatinine and urine pH patient testing. The findings include: 1. Observation of the laboratory on 03/30/23 at 10:15 a.m. revealed three instruments in use for performing urine drug screen, urine creatinine and urine pH. Accessioning personnel were observed receiving and accessioning samples received via FedEx at room temperature. 2. Review of the laboratory's initial establishment studies conducted in 2017 revealed the laboratory established acceptable specimen stability temperature ranges as follows: 18C - 25C for a maximum of 24 hours 2C - 8C for a maximum of seven days -20C for a maximum of 60 days 3. Review of randomly selected final patient test reports revealed the following for the selected patient identification numbers: B42D2437-Collected 08/31/21 at 7:54 am, certified on 09/01/21 at 9:15 a.m. B6311979-Collected 02/16/22 at 8:13 a.m., certified on 02/17/22 at 10:09 a.m. B421721-Collected 05/24/22 at 7:52 a.m., certified on 05/25/22 at 9:39 a.m. B1012547-Collected 10/13/22 at 8:15 a.m., certified on 10/14/22 at 9:33 a.m. B6410429-Collected 02/13/23 at 8:08 a.m., certified on 02/14/23 at 9:41 a.m. B414294-Collected 03/17/23 at 8:07 a.m., certified on 03/20/23 at 9:26 a.m. B50F5542-Collected 03/24/23 at 7:57 a.m., certified on 03/29/23 at 9:39 a.m. 5572-Collected 03/29/23 at 7:51 a.m., certified on 03/30/23 at 10:43 a.m. All patients (8 of 8) were tested past the 24 hour maximum ambient stability study. 4. Interview with the general supervisor on 03/30/23 at 3:30 p.m. confirmed the following: The eight specimens were tested past the established specimen stability study with no corrective action documented. She stated they receive specimens from approximately eight different states via FedEx and test approximately 600 patients/day. Samples are sometimes collected and shipped on Friday and not received in the lab for testing until Monday. She also confirmed there may be delays in shipping and receiving over the holidays.