

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0665512	(X3) Date Survey Completed 04/21/2022
Name of Provider or Supplier Alabama Chd Laboratory System	Street Address, City, State 201 Monroe Street Suite 1040, Montgomery, AL	
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
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of personnel records, Alabama County Health Department Laboratory Systems Policies and Procedures Manual, and an interview with Technical Consultant #2, the Technical Consultant failed to include direct observation of routine patient test performance required for moderate complexity testing evaluation of competency. This was noted from previous survey (11/20/2019) to current survey (04/21/2022) for Vaginal Wet Preparations and Potassium Hydroxide (KOH) testing for a total of 161 Testing Personnel listed on the CMS 209 - Laboratory Personnel Report. The findings include: 1. A review of personnel records revealed the Competency Evaluation Checklist consisted a quiz which covered problem solving skills and assessment of test performance by identifying images for Vaginal Wet Preparations and KOH. This checklist did not include direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. 2. A review of Alabama County Health Department Laboratory Systems Policies and Procedures Manual revealed "...All phases of laboratory testing (preanalytic, analytic, and postanalytic) will be reviewed. Evaluation methods include direct observation, record review, and testing unknown specimens. 1. Direct observation - Personnel will be observed performing testing, QC, reporting, function checks, and maintenance to determine if written procedures are followed. 2. Record review - Quality control and maintenance records will be reviewed for accuracy and completeness. In addition, documentation of "out of control results" and corrective actions taken to correct problems will be reviewed to assess problem solving skills. Patient records will be reviewed to determine if test</p>

reports include initials of testing personnel, date and time of testing. 3. "Unknowns" - In addition to participation in PT programs, "unknowns" (previously analyzed specimens, internal blind testing samples or pictures), will be used to evaluate testing personnel. Testing personnel should maintain a passing score of 80% ..." 3. During an interview on 04/22/2022 at 11:48 AM, Technical Consultant #2 confirmed Competency Assessment being performed on employees does not include all six required criteria.

D6048

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:
Based on a review of personnel records, Alabama County Health Department Laboratory Systems Policies and Procedures Manual, and an interview with Technical Consultant #2, the Technical Consultant failed to include monitoring the recording and reporting of test results. This was noted from previous survey (11/20/2019) to current survey (04/21/2022) for Vaginal Wet Preparations and Potassium Hydroxide (KOH) testing for a total of 161 Testing Personnel listed on the CMS 209 - Laboratory Personnel Report. The findings include: 1. A review of personnel records revealed the Competency Evaluation Checklist consisted a quiz which covered problem solving skills and assessment of test performance by identifying images for Vaginal Wet Preparations and KOH. This checklist did not include monitoring the recording and reporting of test results. 2. A review of Alabama County Health Department Laboratory Systems Policies and Procedures Manual revealed "...All phases of laboratory testing (preanalytic, analytic, and postanalytic) will be reviewed. Evaluation methods include direct observation, record review, and testing unknown specimens. 1. Direct observation - Personnel will be observed performing testing, QC, reporting, function checks, and maintenance to determine if written procedures are followed. 2. Record review - Quality control and maintenance records will be reviewed for accuracy and completeness. In addition, documentation of "out of control results" and corrective actions taken to correct problems will be reviewed to assess problem solving skills. Patient records will be reviewed to determine if test reports include initials of testing personnel, date and time of testing. 3. "Unknowns" - In addition to participation in PT programs, "unknowns" (previously analyzed specimens, internal blind testing samples or pictures), will be used to evaluate testing personnel. Testing personnel should maintain a passing score of 80% ..." 3. During an interview on 04/22/2022 at 11:48 AM, Technical Consultant #2 confirmed Competency Assessment being performed on employees does not include all six required criteria.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on a review of personnel records, Alabama County Health Department Laboratory Systems Policies and Procedures Manual, and an interview with Technical Consultant #2, the Technical Consultant failed to document a review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This was noted from previous survey (11/20/2019) to current survey (04/21/2022) for Vaginal Wet Preparations and Potassium Hydroxide (KOH) testing for a total of 161 Testing Personnel listed on the CMS 209 - Laboratory Personnel Report. The findings include: 1. A review of personnel records revealed the Competency Evaluation Checklist consisted a quiz which covered problem solving skills and assessment of test performance by identifying images for Vaginal Wet Preparations and KOH. This checklist did not include documentation of a review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. 2. A review of Alabama County Health Department Laboratory Systems Policies and Procedures Manual revealed "...All phases of laboratory testing (preanalytic, analytic, and postanalytic) will be reviewed. Evaluation methods include direct observation, record review, and testing unknown specimens. 1. Direct observation - Personnel will be observed performing testing, QC, reporting, function checks, and maintenance to determine if written procedures are followed. 2. Record review - Quality control and maintenance records will be reviewed for accuracy and completeness. In addition, documentation of "out of control results" and corrective actions taken to correct problems will be reviewed to assess problem solving skills. Patient records will be reviewed to determine if test reports include initials of testing personnel, date and time of testing. 3. "Unknowns" - In addition to participation in PT programs, "unknowns" (previously analyzed specimens, internal blind testing samples or pictures), will be used to evaluate testing personnel. Testing personnel should maintain a passing score of 80% ..." 3. During an interview on 04/22/2022 at 11:48 AM, Technical Consultant #2 confirmed Competency Assessment being performed on employees does not include all six required criteria.

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:
Based on a review of personnel records, Alabama County Health Department Laboratory Systems Policies and Procedures Manual, and an interview with Technical Consultant #2, the Technical Consultant failed to include direct observation of performance of instrument maintenance and function checks. This was noted from previous survey (11/20/2019) to current survey (04/21/2022) for Vaginal Wet Preparations and Potassium Hydroxide (KOH) testing for a total of 161 Testing Personnel listed on the CMS 209 - Laboratory Personnel Report. The findings include: 1. A review of personnel records revealed the Competency Evaluation Checklist consisted a quiz which covered problem solving skills and assessment of test performance by identifying images for Vaginal Wet Preparations and KOH. This checklist did not include direct observation of performance of instrument maintenance and function checks. 2. A review of Alabama County Health Department Laboratory Systems Policies and Procedures Manual revealed "...All phases of laboratory testing (preanalytic, analytic, and postanalytic) will be reviewed. Evaluation methods include

direct observation, record review, and testing unknown specimens. 1. Direct observation - Personnel will be observed performing testing, QC, reporting, function checks, and maintenance to determine if written procedures are followed. 2. Record review - Quality control and maintenance records will be reviewed for accuracy and completeness. In addition, documentation of "out of control results" and corrective actions taken to correct problems will be reviewed to assess problem solving skills. Patient records will be reviewed to determine if test reports include initials of testing personnel, date and time of testing. 3. "Unknowns" - In addition to participation in PT programs, "unknowns" (previously analyzed specimens, internal blind testing samples or pictures), will be used to evaluate testing personnel. Testing personnel should maintain a passing score of 80% ..." 3. During an interview on 04/22/2022 at 11:48 AM, Technical Consultant #2 confirmed Competency Assessment being performed on employees does not include all six required criteria.