

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2035148	(X3) Date Survey Completed 03/03/2026
Name of Provider or Supplier Acgt, Inc	Street Address, City, State 35 Waltz Dr, Wheeling, IL	
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 complaint survey was completed on 03/03/2026. The following condition level deficiencies were discovered: D5016 - 42 C.F.R. 493.1210 Condition: Routine chemistry; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.
D5016	<p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory policies and procedures, College of American Pathologists proficiency testing (PT) records, State of Illinois' 210 Illinois Compiled Statutes 25/7-101 Illinois Clinical Laboratory and Blood Bank Act, laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to perform PT biannually in the year of 2025 (see D5217), failed to have a written or electronic request for patient testing by an individual authorized under Illinois state law to order tests or receive test results for eight of eight patients tested (see D5301), failed to establish adequate performance specifications required for accurate and reliable test results (see D5423), and failed to have a system in place that twice a year evaluates and defines the comparison of test results between two of two thermal cycler platforms and two of two Applied Biosystems 3730XL genetic analyzers used for laboratory developed molecular genetics sequencing of Bone Morphogenetic Protein 15 from the beginning of testing in 2025 through the date of survey, 03/03/2026 (see D5775).</p>
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, College of American Pathologists (CAP) proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative; the laboratory failed to perform PT biannually for one of one laboratory developed tests performed, Bone Morphogenetic Protein 15 (BMP15) molecular genetics sequencing, in the year of 2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Proficiency Testing Manual - Test #1", which stated, a. Under "IV. Scope", "[The laboratory] performs alternative testing for Test #1 (SOP 607), and participates in the CAP/[American College of Medical Genetics and Genomics]ACMG Molecular Genetics Sequencing PT test SEC1, administered twice a year." b. Under "V. Procedure", "A. SEC1 proficiency tests will be received for evaluation at [the laboratory] twice a year." 2. Review of CAP PT records revealed the laboratory lacked documentation of CAP PT evaluations for Event 2 of molecular genetics sequencing testing, SEC1, in the year of 2025. Event: Received & Performed: Event 1 - SEC1-A Yes Event 2 - SEC1-B No 3. Interview with the laboratory representative on 03/03/2026, at 10:25 am, confirmed the laboratory failed to perform PT biannually for one of one BMP15 molecular genetics sequencing tests performed in the year of 2025.

D5301

TEST REQUEST

CFR(s): 493.1241(a)

(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:

Based on review of the State of Illinois' 210 Illinois Compiled Statutes (ILCS) 25/7-101 Illinois Clinical Laboratory and Blood Bank Act, laboratory records, and interview with the laboratory representative; the laboratory failed to have a written or electronic request for patient testing by an individual authorized under Illinois state law to order tests or receive test results for eight of eight Bone Morphogenetic Protein 15 (BMP15) molecular genetics sequencing patients tested in 2025. Findings include: 1. Review of Section 7-101 of the Illinois Clinical Laboratory and Blood Bank Act revealed the following: "A clinical laboratory shall examine specimens only at the request of (i) a licensed physician, (ii) a licensed dentist, (iii) a licensed podiatric physician, (iv) a licensed optometrist, (v) a licensed physician assistant, (v-A) a licensed advanced practice registered nurse, (vi) an authorized law enforcement agency or, in the case of blood alcohol, at the request of the individual for whom the test is to be performed in compliance with Sections 11-501 and 11-501.1 of the Illinois Vehicle Code, (vii) a genetic counselor with the specific authority from a referral to order a test or tests pursuant to subsection (b) of Section 20 of the Genetic Counselor Licensing Act, or (viii) a pharmacist in accordance with Section 43.5 of the Pharmacy Practice Act." 2. Review of laboratory test reports for eight of eight patients tested for BMP15 molecular genetics sequencing revealed the laboratory lacked written or electronic request for patient testing by an individual authorized under

Illinois state law to order tests or receive test results as described above. a) Test: BMP15 Report Date: 06/02/2025 Patient ID: MD1-25-09 "Requisitioned By:" [MD1-25-09] b) Test: BMP15 Report Date: 06/02/2025 Patient ID: MD1-25-10 "Requisitioned By:" [MD1-25-10] c) Test: BMP15 Report Date: 06/02/2025 Patient ID: MD1-25-11 "Requisitioned By:" [MD1-25-11] d) Test: BMP15 Report Date: 06/03/2025 Patient ID: MD1-25-12 "Requisitioned By:" [MD1-25-12] e) Test: BMP15 Report Date: 06/03/2025 Patient ID: MD1-25-13 "Requisitioned By:" [MD1-25-13] f) Test: BMP15 Report Date: 06/03/2025 Patient ID: MD1-25-14 "Requisitioned By:" [MD1-25-14] g) Test: BMP15 Report Date: 10/28/2025 Patient ID: MD1-25-15 "Requisitioned By:" [MD1-25-15] h) Test: BMP15 Report Date: 10/28/2025 Patient ID: MD1-25-16 "Requisitioned By:" [MD1-25-16] 3. Interview with the laboratory representative on 03/03/2026, at 12:18 pm, confirmed the laboratory failed to have a written or electronic request for patient testing by an individual authorized under Illinois state law to order tests or receive test results for eight of eight BMP15 molecular genetics sequencing patients tested in 2025.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to establish complete performance specifications required for accurate and reliable test results for one of one laboratory developed test (LDT), Bone Morphogenetic Protein 15 (BMP15) molecular genetics sequencing, prior to report patient results, affecting eight patients. Findings include: 1. Review of laboratory records revealed the laboratory failed to perform a complete verification of performance study for BMP15 molecular genetics sequencing testing prior to reporting patient results. The laboratory failed to address the following characteristics of a verification of performance study for the LDT BMP15: a. Accuracy. b. Precision. c. Analytical sensitivity. d. Analytical specificity to include interfering substances. e. Any other performance characteristic required for test performance. 2. Review of laboratory testing records found eight patient tests were reported for BMP15 molecular genetics sequencing from the beginning of testing in 2025 through the date of survey 03/03/2026. 3. Interview with the laboratory representative on 03/03/2026, at 9:24 am, confirmed the laboratory failed to establish the performance specifications for one of one LDT, BMP15 molecular genetics sequencing, prior to report patient results.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on direct observation, review of laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between two of two thermal cycler platforms and two of two Applied Biosystems (ABI) 3730XL genetic analyzers used for molecular genetics sequencing of Bone Morphogenetic Protein 15 (BMP15) from the beginning of testing in 2025 through the date of survey, 03/03/2026. Findings include: 1. Upon a tour of the laboratory on 03/03/2026, at 8:56 am, two molecular thermal cycler platforms and two ABI 3730XL genetic analyzers used for BMP15 molecular genetics sequencing were observed. Thermal Cycler: Serial Number: 1) S1000 CS016239 2) C1000 Touch CT048945 Genetic Analyzer: Serial Number: 1) ABI 3730XL 17116-024 2) ABI 3730XL 17120-030 2. Review of laboratory records revealed the laboratory lacked instrument-to-instrument comparison documentation for two of two thermal cycler platforms and two of two ABI 3730XL genetic analyzers used for BMP15 molecular genetics sequencing. 3. Interview with the laboratory representative on 03/03/2026, at 9:15 am, confirmed the laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between two of two thermal cycler platforms and two of two ABI 3730XL genetic analyzers used for molecular genetics sequencing of BMP15 from the beginning of testing in 2025 through the date of survey, 03/03/2026.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory policies and procedures, College of American Pathologists proficiency testing (PT) records, laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure adequate establishment of performance specifications as required for accurate and reliable test results (see D6086) and failed to ensure proficiency testing performance biannually (see D6088) for one of one laboratory developed tests performed, Bone Morphogenetic Protein 15 molecular genetics sequencing.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

	<p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure adequate establishment of performance specifications for one of one laboratory developed test, Bone Morphogenetic Protein 15 molecular genetics sequencing, as required for accurate and reliable test results (see D5423).</p>
<p>D6088</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>(e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, College of American Pathologists proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure PT performance biannually for one of one laboratory developed tests performed, Bone Morphogenetic Protein 15 molecular genetics sequencing, in the year of 2025 (see D5217).</p>
<p>D6108</p>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the technical supervisor (TS) failed to evaluate the competency of one of three testing personnel (see D6120) and failed to evaluate and document problem solving skills as part of the competency assessment for three of three testing personnel (see D6126) performing Bone Morphogenetic Protein 15 molecular genetics sequencing, prior to report patient results.</p>
<p>D6120</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the technical supervisor (TS) failed to evaluate the</p>

competency of one of three testing personnel (TP) performing Bone Morphogenetic Protein 15 (BMP15) molecular genetics sequencing, prior to report patient results. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form revealed three TP (TP #1, TP #2, and TP #3) performed BMP15 molecular genetics sequencing testing from the beginning of testing in 2025 through the date of survey, 03/03/2026. 2. Review of laboratory policies procedures revealed the procedure titled "Personnel and Training", which stated, under "6. Competency Assessment:", "The competency of each testing personnel must be assessed following training before the person performs testing." 3. Review of laboratory policies procedures revealed the procedure titled "Personnel Competency Testing / Alternative Assessment - Test #1", which stated, under "IV. Procedure", "A. Competency testing will be performed [for] each qualified testing personnel performed Test #1 at least once per year (initial qualification of new personnel requires two competency tests per year)." 4. Review of laboratory personnel records revealed the TS failed to evaluate the competency of one TP performing BMP15 molecular genetics sequencing. TP: Competency Assessment Performed: #2 No 5. Interview with the laboratory representative on 03/03/2026, at 12:18 pm, confirmed the TS failed to evaluate the competency of one of three TP performing BMP15 molecular genetics sequencing, prior to report patient results.

D6126

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(vi)

(b)(8)(vi) Assessment of problem-solving skills; and

This STANDARD is not met as evidenced by:
Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the technical supervisor (TS) failed to evaluate and document problem solving skills as part of the competency assessment for three of three testing personnel (TP) performing Bone Morphogenetic Protein 15 (BMP15) molecular genetics sequencing, prior to report patient results. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form revealed three TP (TP #1, TP #2, and TP #3) performed BMP15 molecular genetics sequencing testing from the beginning of testing in 2025 through the date of survey, 03/03/2026. 2. Review of laboratory policies procedures revealed the procedure titled "Personnel and Training", which stated, under "6. Competency Assessment:", "The competency of each testing personnel must be assessed following training before the person performs testing Elements of competency assessment include but are not limited to: 6. Evaluation of problem-solving skills". 3. Review of laboratory personnel records revealed the TS failed to evaluate and document problem solving skills as part of the competency assessments of the three TP that performed BMP15 molecular genetics sequencing testing. TP: Problem Solving Skills: #1 "N/A - Did not occur" #2 No competency performed (see D6120) #3 "N/A - Did not occur" 4. Interview with the laboratory representative on 03/03/2026, at 12:18 pm, confirmed the TS failed to evaluate and document problem solving skills as part of the competency assessment for three of three TP performing BMP15 molecular genetics sequencing, prior to report patient results.