

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1028020	(X3) Date Survey Completed 06/25/2026
Name of Provider or Supplier Helgemo And Liou Pediatrics Pa	Street Address, City, State 2040 C Tamiami Trail, Port Charlotte, 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 announced CLIA recertification survey was conducted at Helgemo and Liou Pediatrics, PA on 6/23/26 though 6/25/26. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D6000 493.1403 Condition: Moderate Complexity Laboratory Director D6033 493.1409 Condition: Technical Consultant-Moderate Complexity
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, document review, and interview, it was determined the lab failed to perform negative control material from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology each day of testing (D5449) and the laboratory failed to have an ongoing mechanism to correct problems identified in the analytic systems from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology testing (See 5791).
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on observation, document review, and interview, it was determined the lab failed to perform negative control material from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology each day of testing. Findings included: 1. During tour of lab 6/23/26 at 11:25 AM two different vials labeled positive and one negative vial was observed in Quality Control (QC) box labeled for QIAstat-DX for Bacteriology and Virology. 2. The QIAstat-DX package insert documented "control panel is intended for use as an external positive quality control to monitor the performance". 3. The Policy Manual last approved by the Lab Director 2/4/26 included Individual Quality Control Plan (IQCP) Protocol for QIAstat-DX that requires an external positive and negative control to be analyzed with: a. Each new lot b. Each new shipment c. After system maintenance d. After software upgrades In addition IQCP failure are identified as any problem with testing which would require QC each day of patient testing for 10 days. 4. QIAstat-DX QC logs from 5/16/24 to 6/17/26 failed to document negative control material was tested as required by the manufacturer and lab policy. The QIAstat-DX QC logs from 5/14/25 to 6/18/25 documented lot # 181018188 was in use but patient report #1 with test date of 5/14/25 document the lot # used for this patient testing was documented as 181016603 which was the previous lot # in use until 4/15/25 and from 1/20/26 to 3/31/26 Lot # 181035016 was in use but patient report #3 with test date of 1/27/26 documented the lot # used for this patient testing was documented as 181033035, no QC for this lot # was found documented on the QC log from 5/16/24 to 6/17/26. For patient report #5 with test date of 3/30/26 lot # used for this patient testing was documented as 181043793, this lot # was not put into use based on the QC log until 3/31/26. 5. Patient QIAstat-DX Bacteriology and Virology reports for Patient #1 (tested 5/14/25), # 2 (tested 6/17/25), #3 (tested 1/27/26), #4 (tested 4/30/26), and #5 (tested 3/30/26) failed to document negative controls had been performed. 5. Testing Person (TP) # G confirmed on 6/23/26 at 3:00 PM there was no documentation that the laboratory performed negative control material from 5/16/24 to 6/17/26 and that the lab failed to perform external QC for each new lot #. TP # C (identified by TP #G as one of the prime operators of the QIAstat-DX patient testing) stated via phone call on 6/23/26 at 3:30 PM no negative external QC material was tested and every cartridge of a lot was used prior to opening new lot number box.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on document review and interview, it was determined the laboratory failed to have an ongoing mechanism to correct problems identified in the analytic systems from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology testing. Findings included: 1. The lab Quality Assessment (QA) plan was last approved by the Lab Director 2/4/26. The plan included a monthly scheduled of tasks to be performed. The lab used a monthly QA report which included monthly review of Individual Quality Control Plan (IQCP) and Competency. Three of three monthly QA reports reviewed 11/2024 (Lab Director signed 12/2024), 7/2025 (Lab Director signed 8/2025), and 3/2026 (Lab Director signed 4/2026) failed to identify and correct the

	problem of the lab's failure to perform negative control material from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology each day of testing. (See D5449) 2. Testing Person # G confirmed 6/23/2026 at 3:00 PM the laboratory QA monthly reviews had not identified or corrected the failure to perform external negative quality control material. 3. The Lab Director stated via email on 6/25/2026 at 8:57 AM the lab had not been aware external negative control material was required.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation and record review, the Lab Director failed to have a policy to be onsite once every six months and failed to document any onsite visits from 1/1/2025 to 6/23/2026 (See D6005), the laboratory failed to provided quality laboratory services for analytic qualitative Bacteriology and Virology testing from 4/25/24 to 6/23/26 (See D6007), and failed to ensure a quality assessment program was maintained to identify failures in quality from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology testing (See D6020).
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, it was determined the Lab Director failed to establish a policy to be onsite once every six months and failed to document any onsite visits from 1/1/2025 to 6/23/2026. Findings Included: 1. The Policy and Procedure manual last approved by the Lab Director 2/4/2026 failed to contain a policy to be onsite every six months and to document activities during onsite visits. 2. The Lab Director stated via email 6/25/2026 at 8:57 AM he reviewed documentation monthly but did not indicate he performed any six month onsite visits with documentation of activities while in the lab testing area.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

	This STANDARD is not met as evidenced by: Based on observation, document review, and interview, it was determined the Lab Director failed to ensure the laboratory provided quality laboratory services for analytic qualitative Bacteriology and Virology testing from 4/25/24 to 6/23/26. Findings included: The Lab Director failed to ensure the lab performed negative control material from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology each day of testing (See D5449).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on document review and interview, it was determined the Lab Director failed to ensure quality assessment programs was maintained to assure the lab identified failures in quality from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology testing. Findings included: The Lab Director failed to ensure the laboratory had an ongoing mechanism to correct problems identified in the analytic systems from 4/25/24 to 6/23/26 for the qualitative Bacteriology and Virology testing. (See D5791)
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interview, it was determined the Technical Consultant failed to ensure two (TP- E and TP-G) of seven testing personnel (TP-A, B, C, D, E, F, and G) training was received for testing performed (See D6045) and failed to ensure the competency of all seven of seven testing personnel (TP-A, B, C, D, E, F, and G) and assuring that the staff maintained their competency (See D6046).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (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; This STANDARD is not met as evidenced by: Based on document review and interview, it was determined the Technical Consultant failed to ensure for two (TP- E and TP-G) of seven testing personnel (TP-A, B, C, D, E, F, and G) training was received for testing performed. Findings included: 1. The Policy Manual last approved by the Lab Director 2/4/2026 included policy for training

and competency documented Initial Training was to be documented at the completion of each training activities. The Job Description for the Technical Consultant indicated responsibility for identifying training needs. 2. The Laboratory Personnel Report (CLIA) signed by the Lab Director 6/11/2026 listed seven TP (TP-A, B, C, D, E, F, and G) . The Lab DIrector was listed as the Technical Consultant (TC). 3. Personnel Record for TP-E training record dated 6/2/25 to 9/2/25 failed to include any documentation by the TC or any other staff. 4. On 6/23/2026 at 1:05 PM TP # G stated that they performed Calibration of the Emerald hematology analyzer, but there was no training record presented for TP-G. 5. The Lab Director/Technical Consultant verified via email on 6/25/26 at 8:57 AM he was aware personnel policies were to be followed.

D6046

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

(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
Based on document review and interviews, it was determined the Technical Consultant failed to ensure the competency of all seven of seven testing personnel (TP-A, B, C, D, E, F, and G) and assured that the staff maintained their competency. Findings included: 1. The Policy Manual last approved by the Lab Director 2/4/2026 included policy for training and documented competency was the responsibility of Technical Consultant and was to be documented at the completion training, six months, and twelve months in the first year and yearly thereafter. Assessment of competency was to include direct observation, monitoring of test reports and worksheets, proficiency samples, and problem solving. 2. The Laboratory Personnel Report (CLIA) signed by the Lab Director 6/11/2026 listed seven TP (TP-A, B, C, D, E, F, and G) . The Lab DIrector was listed as the Technical Consultant (TC). 3. Personnel Record for TP-A, B, C, D, E, and F competency records documented competencies were performed and reviewed by TP-G (who did not qualify to be a Technical Consultant). The Lab Director/Technical Consultant signed the competencies without specific date of signing off competencies. 4. On 6/23/2026 at 1: 05 PM TP # G stated she performed Calibration of the Emerald hematology analyzer, but there was no competencies record presented for TP-G. 5. The Lab Director /Technical Consultant verified via email on 6/25/26 at 8:57 AM he was aware personnel policies were to be followed.