

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0712431	(X3) Date Survey Completed 09/26/2023
Name of Provider or Supplier Long Hollow Family Practice Pc	Street Address, City, State 450 Professional Park Dr Ste E, Goodlettsville, 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	During a recertification survey on 09/26/2023 the laboratory was found not be in compliance with the following CLIA conditions: 493.1250 Condition: Hematology 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency test (PT) records and staff interview, the laboratory director and testing personnel failed to sign the complete blood count (CBC) PT attestation statements for seven of seven events reviewed from 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's API PT records for CBC testing revealed the attestation statements were maintained electronically on the API website on the date of the survey (09/26 /2023) as follows for seven of seven events reviewed: 2021 Events two and three 2022 Events one, two, and three 2023 Events one and two None of the attestation statements had been signed by either the laboratory director or testing personnel. 2. Interview on 09/26/2023 at 2:15 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory director and testing personnel did not sign the attestation statements that were submitted electronically on the API website for the PT events for CBC testing in 2021, 2022, and 2023.</p>
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)

The laboratory must test samples the same number of times that it routinely tests patient samples.

This STANDARD is not met as evidenced by:

Based on review of laboratory American Proficiency Institute (API) proficiency testing (PT) records, lack of policy, and staff interview, the laboratory failed to test PT samples the same number of times that patient samples were tested for complete blood count (CBC) testing for two API PT events (two of seven reviewed) in 2022 and 2023. The findings include: 1. Review of PT records for 2022 event one revealed PT samples were performed multiple times as indicated below: #01 03/28/2022 12:44 and 13:58 #02 03/28/2022 12:45 and 14:01 #03 03/28/2022 13:00 and 14:14 #04 03/28/2022 14:06 and 03/29/2023 9:24 am 2. Review of PT records for 2023 event two revealed PT samples were performed multiple times as indicated below: #06 07/26/2023 13:42, 13:44, 13:48, 15:58. #07 07/26/2023 13:52, 13:54, 13:57, 14:01. #08 07/26/2023 14:15, 14:19, 14:21, 14:28. #09 07/26/2023 14:39, 14:43, 14:46, 14:49 #10 07/26/2023 14:52, 14:54, 14:57, 14:58. 3. There was no policy that required repeat testing of patient samples on the date of the survey (09/26/2023). 4. Interview on 09/26/2023 at 2:15 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory did not test PT samples the same number of times that patient samples are routinely tested in 2022 and 2023.

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of daily quality control records, lack of records, and staff interview, the laboratory failed to retain manufacturer package inserts for quality controls used for the Sysmex XN 330 CBC instrument in 2022 or 2023. The findings include: 1. Observation of the laboratory on 09/26/2023 at 9:22 am revealed a Sysmex XN 330 (serial # 12114) in use for patient CBC testing. 2. Review of daily quality control instrument printouts revealed the following: Lot 1351 in use on 01/04/2022 Lot 2070 in use on 06/01/2022 Lot 2322 in use on 01/10/2023 Lot 3041 in use on 05/18/2023 3. No manufacturer control assay sheets were available on the date of the survey for lots 1351, 2070, 2322, or 3041. 4. Interview on 09/26/2023 at 3:00 pm with the laboratory director testing person one, and laboratory liaison confirmed the laboratory failed to retain quality control manufacturer assay sheets for a period of two years for the Sysmex XN 330 CBC instrument in 2022 and 2023.

D5024

HEMATOLOGY

CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

	<p>Based on record request and staff interview the laboratory failed to establish a written policy or procedure to assess testing personnel competency (See D5209), failed to document review of PT performance evaluations (See D5221), failed to establish a written policy for Quality Assessment (See D5291), failed to have a complete procedure for the Sysmex XN 330 instrument (See D5403), failed to monitor and define environmental criteria for the use of the Sysmex XN 330 (See D5413), and failed to have control procedures in place for controls used for the Sysmex XN 330 (See D5441).</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory failed to establish written policies and procedures to assess competency for personnel that perform CBC patient testing. The findings include: 1. There was no competency policy available on the date of the survey (09/26/2023). 2. Interview on 09/26/2023 at 3:00 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory did not have a personnel policy established to assess competency for personnel that perform CBC patient testing.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory PT records and staff interview, the laboratory failed to document review of the performance evaluation provided by API in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's API CBC PT records revealed no documented review or evaluation for six of seven events (2021 events two and three, 2022 events one and three, 2023 events one and two). 2. Interview on 09/26 /2023 at 2:15 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory did not document review of the performance evaluations provided by API for six of seven PT events in 2021, 2022, and 2023.</p>
<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on lack of policy and staff interview, the laboratory failed to establish a written</p>

policy or procedure for quality assessment. The findings include: 1. A Quality assessment policy was not available on the date of the survey (09/26/2023). 2. Interview on 09/26/2023 at 3:00 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory did not have a written policy or procedure for quality assessment.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of laboratory procedure, and staff interview, the laboratory procedure failed to contain all required elements for the Sysmex XN 330 CBC analyzer. The findings include: 1. Observation of the laboratory on 09/26/2023 at 9:22 am revealed a Sysmex XN 330 (serial # 12114) in use for CBC patient testing. 2. Review of the laboratory procedure in use for the Sysmex XN 330 instrument CBC patient testing revealed the procedure did not include the following required elements: Step by Step performance of the procedure including the interpretation of results. Calibration procedures. Control procedures. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. Reference intervals. Laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. Description of the course of action to take if a test system becomes inoperable. 3. Interview on 09/26/2023 at 3:00 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory procedure in use for the Sysmex XN 330 CBC instrument did not include the required elements.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the manufacturer operator's manual, review of laboratory records, and staff interview, the laboratory failed monitor room temperature and humidity in the area where the Sysmex XN 330 CBC instrument was in use, failed to monitor the storage temperature of the refrigerator where CBC controls were stored in 2021 and 2022, and failed to define acceptable temperature ranges for the refrigerator where the controls were stored in 2023. The findings include: 1. Observation of the laboratory on 09/26/2023 at 9:22 am revealed a Sysmex XN 330 (serial # 12114) in use for CBC patient testing and a refrigerator in use for storage of CBC controls. 2. Review of the Sysmex XN 330 instrument Operator's Manual revealed environment specifications as follows: Operating Ambient temperature 15-35 degrees Celsius. Operating Relative humidity of 20-85%. Control Sample Storage 2-8 degrees Celsius. 3. Review of the laboratory environmental records revealed the following: Room temperature and humidity in the area where the Sysmex XN 330 instrument was in use was not monitored in 2021, 2022, or 2023. There were no temperature records available for 2021 or 2022 for the refrigerator where the controls were stored. The 2023 temperature records did not define the acceptable ranges for storage of the controls. 4. Interview on 09/26/2023 at 3:00 pm with the laboratory director, testing person one, and laboratory liaison confirmed the following: The laboratory did not monitor room temperature and humidity in the area where the Sysmex XN 330 CBC instrument was in use in 2021, 2022, and 2023. The laboratory did not have records for monitoring refrigerator temperatures where the CBC controls were stored in 2021 and 2022. The laboratory did not define the temperature ranges for the refrigerator where the controls were stored in 2023.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, lack of records available, and staff interview, the laboratory failed to have control procedures for the controls for the Sysmex XN CBC instrument used for patient testing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 09/26/2023 at 9:22 am revealed a Sysmex XN 330 (serial #12114) in use for patient CBC testing. 2. A laboratory control procedure that included monitoring accuracy and precision over time, number, type, and frequency of control material, detection of immediate errors, and documentation

	<p>of control procedures was not available on the date of the survey (09/26/2023). 3. Interview on 09/26/2023 at 3:00 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory failed to have a control procedure in place in 2021, 2022, and 2023.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure all PT reports were reviewed (See D6018), failed to ensure the laboratory had quality control procedures (See D6020), failed to ensure the laboratory had an established quality assessment procedure (See D6021), and failed to ensure a policy and procedure for personnel competency was established (See D6030).</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory PT records and staff interview, the laboratory director failed to ensure that all proficiency testing reports were reviewed in 2021, 2022, and 2023 (Refer to D2009). The findings include: 1. Review of the laboratory's API CBC PT records revealed no documented review or evaluation for six of seven events (2021 events two and three, 2022 events one and three, 2023 events one and two). 2. Interview on 09/26/2023 at 2:15 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory director did not document review of the performance evaluations provided by API for six of seven PT events in 2021, 2022, and 2023.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, lack of records available, and staff interview, the laboratory director failed to ensure that the laboratory had quality control procedures for the use of controls for the Sysmex XN 330 CBC instrument used for patient testing in 2021, 2022, and 2023 (Refer to D5441). The findings include: 1. Observation of the laboratory on 09/26/2023 at 9:22 am revealed a Sysmex XN 330 (serial #12114) in use for patient CBC testing. 2. A laboratory control procedure that included monitoring accuracy and precision over time, number, type, and frequency of control material, detection of immediate errors, and documentation of control procedures was not available on the date of the survey (09/26/2023). 3. Interview on 09/26/2023 at 3:00 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory director failed to ensure a quality control procedure was in place for the Sysmex XN 330 CBC instrument in 2021, 2022, and 2023.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on lack of policy, lack of documented reviews, and staff interview, the laboratory director failed to ensure a quality assessment program was established for quality assessment in 2021, 2022, and 2023 (Refer to D5291). The findings include: 1. A quality assessment policy was not available on the date of the survey (09/26/2023). 2. Documented quality assessment reviews were not available on the date of the survey (09/26/2023). 2. Interview on 09/26/2023 at 3:00 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory director did not ensure a written policy or procedure for quality assessment was established in 2021, 2022, and 2023.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Personnel Report (CLIA) (Form CMS-209), personnel record review, and staff interview, the laboratory director failed to ensure a policy and procedure was established for personnel competency assessments in 2021, 2022 and 2023 (Refer to D5209). The findings include: 1. Review of the Form CMS-209 revealed three testing personnel for CBC patient testing. 2. Laboratory personnel policy for competency assessment was not available on the date of the survey (09/26/2023). 3. Interview on 09/26/2023 at 3:00 pm with the laboratory director, testing person one, and laboratory liaison confirmed the laboratory director failed to ensure a policy and procedure for personnel competency assessment was in place in 2021, 2022, and 2023.