Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0934097	11/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hh Physician Care	13596 Highway 231/431, Suite 2, Hazel Green, 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
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 a review of the Strep Selective Agar (SSA) quality control (QC) records, the "Media Quality Control" procedure, and an interview with the Practice Administrator, the surveyor determined the laboratory failed to perform the SSA QC, as per policy. This was noted in QC records from August 2017 thru November 2019. The findings include: 1. A review of the Media Quality Control policy implemented after the previous CLIA survey, and signed by the Laboratory Director on 8/28/2017, revealed the following: "... 2. Strep Agar plates: S. [Strep] Pyogenes (A) control product will be applied to the agar plate, placed in the incubator 24-48 hours to determine if it will

	support growth. Expected results: growth with hemolysis S. [Strep] Agalactiae (B) control product will be applied to the agar plate, placed in the incubator 24-48 hours to determine if it will support growth. Expected results: growth without hemolysis ... ... We will keep our labels taken from the products on a form that will indicate growth with hemolysis, growth without hemolysis, or no growth. ...". 2. A review of the SSA QC records revealed the following failures in adherance to the above QC policy: A) August 2017-November 2019: The testing personnel circled "Y" (Yes) for growth on the QC records, and failed to specify "growth with hemolysis" or "growth without hemolysis" for the individual organisms, as per policy. B) 8/29/2017-3/20/2018 and 7 /6-8/15/2018, : Only one QC organism (S. pyogenes or S. agalactiae) used to QC each new lot number (#) of media (not both species, as per policy). C) 3/21/2019: The testing personnel circled "N" (No) for growth for S. agalactiae on Lot #1804700; despite the QC, failure this lot # was in use 3/20-4/30/2018. D) 11/12-11/15/2018, 12 /2-12/9/2018, 2/25-2/26/2019, and 3/14-3/24/2019: Testing personnel utilized new lot #'s of SSA before the QC was performed. E) 4/9-5/20/2019: No documentation of QC verifying ability to support growth and produce expected reactions on Health Link SSA F) 6/7-11/12/2019: No documentation of QC verifying ability to support growth and produce expected reactions on the SSA when the laboratory switched to a new manufacturer (Hardy Diagnostics and BBL). 3. In an interview on 11/13/2019 from 3: 30-4:00 PM the surveyor reviewed and confirmed the above noted findings with the Practice Administrator. .
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Strep Selective Agar (SSA) quality control (QC) records, the "Media Quality Control" procedure, and an interview with the Practice Administrator, the surveyor determined the laboratory failed to perform and document QC verifying the ability of new lot numbers of SSA to support growth and produce expected reactions before use for patient testing. This was noted in QC records from November 2018 thru November 2019. The findings include: 1. A review of the Media Quality Control policy implemented after the previous CLIA survey, and signed by the Laboratory Director on 8/28/2017, revealed the following: "... 2. Strep Agar plates: S. [Strep] Pyogenes (A) control product will be applied to the agar plate, placed in the incubator 24-48 hours to determine if it will support growth. Expected results: growth with hemolysis S. [Strep] Agalactiae (B) control product will be applied to the agar plate, placed in the incubator 24-48 hours to determine if it will support growth. Expected results: growth without hemolysis ... 2. A review of the SSA QC records revealed the laboratory failed to perform and document QC verifying the ability of new lot numbers of SSA to support growth and produce expected reactions before use for patient testing, as follows: A) 11/12-11/15/2018, 12/2-12/9/2018, 2/25-2/26/2019, and 3/14-3/24/2019: Testing personnel utilized new lot #'s of SSA before the QC verifying the ability to support growth and produce expected reactions was performed.

	B) 4/9-5/20/2019: No documentation of QC verifying ability to support growth and produce expected reactions on Health Link SSA C) 6/7-11/12/2019: No documentation of QC verifying ability to support growth and produce expected reactions on the SSA when the laboratory switched to a new manufacturer (Hardy Diagnostics and BBL). 3. In an interview on 11/13/2019 from 3:30-4:00 PM the surveyor reviewed and confirmed the above noted findings with the Practice Administrator, who explained review of the QC records has been neglected because of the implementation of a new Laboratory Information System (LIS). The surveyor then asked how many patient cultures had been performed during the months when there was no QC as per the above policy. Because of the changes in the LIS, only records for August thru November 2019 were available; 282 patient throat cultures were performed during that period. 4. This is a repeat deficiency. .
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of quality assurance (QA) and Strep Selective Agar (SSA) quality control (QC) records, the "Media Quality Control" procedure, and an interview with the Practice Administrator, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems from August 2017 thru November 2019. The findings include: 1. A review of the August 2017 thru October 2019 monthly QA checklists under "...Analytical System" revealed, "...Quality Control is run according to our written procedures ...". The testing personnel checked "Yes" to this QA indicator every month. 2. A review of the Bacteriology records and the "Media Quality Control" procedure revealed the laboratory failed to perform the SSA QC as per policy from August 2017 thru November 2019. (Refer to D5403 and D5477.) The laboratory had failed to identify this problem during the monthly QA reviews. 3. In an interview on 11/13/2019 from 3:30-4:00 PM the surveyor reviewed and confirmed the above noted findings with the Practice Administrator. SURVEYOR ID #32558 Licensure and Certification Surveyor