SURVEY TRACKING TOOL

Date of survey- 7/22/2019 **Surveyor -** [redacted]

POC Required?- YES

SOD Sent- 8/21/2019

Letter Sent- 8/21/2019

POC Due- 9/11/2019

POC Recived- 9/03/2019

POC Accepted- 9/10/2019 **Acceptance Letter Sent-** 9/11/2019

Refusal Sent-

Second POC Received- ✓ **Acceptance Letter-**

Refusal Sent-

670 Printed- 9/11/2019

Kit Closed- 9/11/2019

Packet Completed- 9/4/2019

Cert. Kit Uploaded- 9/4/2019

NOTES:

Facility: COLUMBUS WOMENS HEALTH ORG

CLIA#: [redacted]

STATE#: [redacted]

GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Brian P. Kemp, Governor

Frank W. Berry, Commissioner

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-656-4507 | www.dch.georgia.gov

September 11, 2019

Dr Bruse Norman, Laboratory Director
Columbus Womens Health Org
3850 Rosemont Drive
Columbus, GA 31904

CLIA No.: 11D2025053

Dear Dr. Norman:

Thank you for submitting your plan of correction outlining the measures you have taken to assure that deficiencies noted during the CLIA survey are corrected.

The plan is acceptable and will become a part of the record and files of your laboratory. As the agency having responsibility for recommending certification, we must insist that this plan of correction be carried out.

If we can be of assistance during this time, please let us know.

Sincerely,

Christel Benn-Griffith, Director
Diagnostic Services Unit
Healthcare Facility Regulation Division

CBG/glr

GEORGIA DEPARTMENT
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IMPORTANT NOTICE – ACTION NECESSARY

August 21, 2019

Dr Bruse Norman, Laboratory Director
Columbus Womens Health Org
3850 Rosemont Drive
Columbus, GA 31904

[redacted]

RE: CONDITION-LEVEL DEFICIENCIES

Dear Dr. Norman:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The **Healthcare Facility Regulation Division (HFRD)** conducted Recertification survey of your laboratory that was completed on July 22, 2019.

Please note that this routine survey was expedited because your laboratory's CLIA certificate has expired or is about to expire. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following Conditions were not met:

D6000 - 42 C.F.R. § 493.1403 Condition:	Laboratories performing moderate complexity testing; laboratory director;
D6033 - 42 C.F.R. § 493.1409 Condition:	Laboratories performing moderate complexity testing; D6153 - 42 C.F.R. § 493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor;

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to

Christel Benn-Griffith
Program Director, Diagnostic Services Unit
Healthcare Facility Regulation Division
2 Peachtree Street, N.W., 31st floor
Atlanta, GA 30303-3142

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the State agency at any time to address complaints or other noncompliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact me at .

Sincerely,

Christel Benn Griffith, BSMT(ASCP)
Program Director
Diagnostic Service Unit
Healthcare Facility Regulation Division

CBG:gr