SURVEY TRACKING TOOL

Date of survey- 9/27/2017 **Surveyor -** Dana Gannon

POC Required?- (YES)

SOD Sent- 10/11/2017

Letter Sent- 10/11/2017

POC Due- 10/21/2017

POC Recived- 10/20/2017

POC Accepted- 10/26/2017

Second POC Received- N/A

670 Printed- 10/31/2017

Kit Closed- 10/31/2017

Packet Completed- 10/31/2017

Cert. Kit Uploaded- 10/31/2017

Acceptance Letter Sent- _____

Refusal Sent- _____

Acceptance Letter- _____

Refusal Sent- _____

NOTES:

Facility: Columbus Womens Health Org

CLIA#: [redacted]

STATE#: _____

GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Nathan Deal, Governor

Frank Berry, Commissioner

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

October 31, 2017

Dr. Sacheen Nathan, M.D., Laboratory Director
Columbus Womens Health Org
3850 Rosemont Drive
Columbus, GA 31904

CLIA No.: 11D2025053

Dear Dr. Nathan:

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, MT (ASCP)
Program Director
Diagnostic Services Unit
Healthcare Facility Regulation Division

cbg:cg

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IMPORTANT NOTICE – ACTION NECESSARY

October 11, 2017

Dr Sacheen Nathan, Laboratory Director
Columbus Womens Health Org
3850 Rosemont Drive
Columbus, GA 31904

[redacted]

RE: STANDARD-LEVEL DEFICIENCIES

Dear Dr. Nathan:

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 State Of Ga, Healthcare Facility Regulation Division conducted a Recertification survey of your laboratory that was completed on September 27, 2017. Enclosed is form CMS-2567, Statement of Deficiencies, listing the deficiencies found during the survey. The deficiency statement references the CLIA regulations at 42 C.F.R. § 493.

You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Please return the completed form CMS-2567, dated and signed by the director, within 10 days of receipt of this notice.

Regulations at 42 C.F.R. § 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a plan of correction that is acceptable to CMS (Centers for Medicare & Medicaid Services) in content and time frames. Further, regulations at 42 C.F.R. § 493.1816 require all deficiencies to be corrected within 12 months after the last day of the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.

If your laboratory does not respond timely to this request, or if your laboratory submits a Plan of Correction that is not acceptable in content and time frames, or if your laboratory does not demonstrate compliance with all CLIA requirements by the specified completion date, we will recommend to CMS imposition of principal sanctions, i.e., suspension, limitation and/or revocation of

your laboratory's CLIA certificate and concurrent cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. § 493.1816.

Your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies. For your information, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

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 Of Ga, Healthcare Facility Regulation Division at any time to address complaints or other non-compliance 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 404-657-5447 .

Sincerely,

Christel Benn-Griffith, MT(ASCP)
Diagnostic Services Director
Department of Community Health
Healthcare Facility Regulation Division

Enclosure: CMS-2567, Statement of Deficiencies

CBG:cg