

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0387698	<b>(X3) Date Survey Completed</b>  04/27/2018
<b>Name of Provider or Supplier</b>  Genesis Health Group- Eldridge	<b>Street Address, City, State</b>  301 North 4th Avenue, Eldridge, IA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvement Amendments (CLIA) Application (Form CMS-116), Abbott Cell Dyn 1800 operator's manual, maintenance logs, and confirmed by laboratory personnel identifiers #6 and #7 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 04/27/2018, the laboratory failed to perform and document Abbott Cell Dyn 1800 complete blood count (CBC) analyzer maintenance as defined by the manufacturer for 41 out of 314 days, 20 out of 65 weeks, and two out of 15 months from January 3, 2017- March 30, 2018. The findings include: 1. Review of the CLIA Application indicated that the laboratory holds hours of operation Monday through Friday of each week. 2. The Abbott Cell Dyn 1800 operator's manual listed the following daily maintenance activities: *Daily Startup *Daily Shutdown 3. Review of the laboratory's maintenance logs revealed that the laboratory did not document the daily startup on the following dates: 05/31/2017, 06/08/2017, 07/05- 07/06/2017, 11/17/2017, 11/23/2017, 12/19/2017, 01/09- 01/10/2018, 01/12/2018, 01/15/2018. 4. Review of the laboratory's maintenance logs revealed that the laboratory did not document the daily shutdown on the following dates: 01/19/2017, 01/25-01/27/2017, 02/16- 02/17/2017, 04/06- 04/07/2017, 05/12/2017, 05/30- 05/31/2017, 06/05/2017, 06/07- 06/09/2017, 06/22- 06/23/2017, 07/03/2017, 07/05- 07/06/2017, 07/28/2017, 07/31/2017, 09/21/2017, 09/25- 09/26/2017, 09/29/2017, 10/20/2017, 11/09- 11/10/2017, 11/23/2017, 12/19/2017, 12/21/2017, 01/09- 01/12/2018, 01/15/2018, 01/25/2018, 03/16/2018, and 03/23/2018. 5. The Abbott Cell Dyn 1800 operator's manual listed the following weekly maintenance activities: *Auto Clean *Clean Aspiration Probe Exterior 6. Review of the</p>

laboratory's maintenance logs revealed that the laboratory did not document the auto clean during the weeks of 02/20/2017, 10/02/2017, 12/18/2017, and 01/08/2018. 7. Review of the laboratory's maintenance logs revealed that the laboratory did not document cleaning of the aspiration probe exterior during the weeks of 01/09/2017, 02/27/2017, 03/06/2017, 04/17/2017, 06/05/2017, 06/12/2017, 07/24/2017, 07/31/2017, 08/28/2017, 10/02/2017, 11/20/2017, 11/27/2017, 12/04/2017, 12/11/2017, 12/18/2017, 12/26/2017, 01/02/2018, 01/08/2018, and 01/22/2018. 8. The Abbott Cell Dyn 1800 operator's manual listed the following monthly maintenance activities: \*Rinse Lyse Inlet Lines \*Rinse Reagent Inlet Lines 9. Review of the laboratory's maintenance logs revealed that the laboratory did not document monthly maintenance activities for the months of September and December 2017. 10. At the time of the survey, personnel identifiers #6 and #7 confirmed that the laboratory did not have documented maintenance for the dates and time frames listed previously.

**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:

A. Based on review of the laboratory's quality assurance policy, lack of chart audits, and confirmed by laboratory personnel identifier # 2 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 04/27/2018, the laboratory director failed to ensure that the laboratory maintained the quality assessment program for four out of four time periods from January 2017- December 2017. The findings include: 1. The "Genesis Health Group Quality Assurance Review" policy stated, "Quality assurance reviews will be done on at least a quarterly basis." 2. At the time of the survey, the laboratory did not have documentation indicating that quarterly quality assurance reviews had been performed from January 2017- December 2017. B. Based on review of the the laboratory's Monthly QA Review policy, hematology maintenance logs, and confirmed by laboratory personnel identifiers #6 and #7 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 04/27/2018, the laboratory director failed to ensure that the laboratory maintained the quality assessment program for 17 out of 65 weeks from January 3, 2017- March 30, 2018. The findings include: 1. The "Monthly QA Review- Eldridge Lab" policy stated, "Levy- Jennings for CBC- Check weekly for shifts and trends." 2. Review of the Abbott Cell Dyn maintenance logs revealed that the laboratory did not document checks for shifts and trends during the weeks of 02/06/2017, 02/20/2017, 03/06/2017, 03/20/2017, 03/27/2017, 06/12/2017, 07/24/2017, 10/02/2017, 11/20/2017, 11/27/2017, 12/04/2017, 12/11/2017, 12/18/2017, 12/26/2017, 01/02/2018, 01/08/2018, and 01/22/2018. 3. At the time of the survey, personnel identifiers #6 and #7 confirmed that the laboratory did not have documentation indicating that weekly checks for shift and trends had been performed during the time frames previously mentioned.