

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

GeneSTAT Molecular Diagnostics LLC
180 North 300 East St Suite 201
Saint George
Utah
84770
USA

Holds Certificate No:

FM 553772

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Manufacture, and Distribution of Analytical Equipment and Reagents for Nucleic Acid detection.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2010-04-06

Latest Revision Date: 2019-11-11

Effective Date: 2019-03-11

Expiry Date: 2022-03-10

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Certificate No: **FM 553772**

Location

GeneSTAT Molecular Diagnostics LLC
180 North 300 East St Suite 201
Saint George
Utah
84770
USA

Registered Activities

Design, Manufacture, and Distribution of Analytical Equipment and Reagents for Nucleic Acid detection.

GeneSTAT Molecular Diagnostics LLC
1414 E 3850 S
St. George
Utah
84790
USA

Quality control testing of DxNA production batches. Burn in testing of new analytical platforms and assay product development.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.