

**QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003** 

This is to certify that:

PrimeraDx, Inc. 171 Forbes Blvd, Suite 2000 Mansfield Massachusetts 02048 USA

Holds Certificate No: FM 578067

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

The design, manufacturing and distribution of multiplex instrumentation and assays (including reagent kits) for molecular diagnostics.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally Registered: 01/11/2012 Effective Date: 01/11/2012 Expiry Date: 01/10/2015



CMDCAS Recognized Registrar



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