

This is to certify that the Quality Management System of:

Golden West Diagnostics LLC

27617 Commerce Center Drive Temecula, CA 92590 United States of America

Central function listed above. See appendix for additional locations

applicable to:

Manufacture and distribution of calibrators, controls base material, and biological materials for use in research and in vitro diagnostic applications.

has been assessed and approved by National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016



For and on behalf of NQA, USA



Certificate Number: 16596

EAC Code: 12

Certified Since: September 12, 2016
Valid Until: September 11, 2025
Reissued: September 30, 2022

Cycle Issued: September 30, 2022

Prior Cycle Exp Date: September 11, 2022

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Appendix to Certificate Number: 16596

Includes Facilities Located at:

Golden West Diagnostics LLC

Certificate Number 16596 27617 Commerce Center Drive Temecula, CA 92590 United States of America

Golden West Diagnostics LLC

Certificate Number 16596 42191 Sarah Way Temecula CA 92590 United States of America

Golden West Diagnostics LLC

Certificate Number 16596 571 Crane Street, Unit G Lake Elsinore CA 92530 United States of America Administration

Manufacture and Distribution of calibrators, controls and biological materials for use in research and in vitro diagnostic applications

The manufacture of raw materials for use in research and in vitro diagnostic applications

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