

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

ILLUMINA CLINICAL SERVICES LABORATORY
5200 ILLUMINA WAY
SAN DIEGO, CA 92122-4616

CLIA ID NUMBER

05D1092911

EFFECTIVE DATE

10/27/2021

EXPIRATION DATE

10/26/2023

LABORATORY DIRECTOR

STEWART W COMER M.D.

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Monique Spruill
Monique Spruill, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

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If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
ROUTINE CHEMISTRY (310)	02/14/2013		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CLIA ID Number: 05D1092911

ILLUMINA CLINICAL SERVICES LABORATORY
5200 ILLUMINA WAY
SAN DIEGO, CA 92122-4616

STATE AGENCY ADDRESS AND PHONE NUMBER:

CA DHS/LABORATORY FIELD SERVICES
DIVISION OF LABORATORY SCIENCE
320 WEST 4TH STREET SUITE 890
LOS ANGELES, CA 90013-2398
(213)620-6160

LABORATORY MAILING ADDRESS:

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Illumina, Inc.
5200 Illumina Way
San Diego
California
92122
USA

Holds Certificate Number:

FM 565017

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

Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression and PCR - products, instruments and software - used for genetic analysis.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2011-01-14

Latest Revision Date: 2022-11-22

Effective Date: 2022-12-06

Expiry Date: 2025-12-05

Page: 1 of 2



...making excellence a habit.™

Certificate No: FM 565017

Location	Registered Activities
ILLUMINA, INC. 524 Genomic Drive Madison Wisconsin 53719 USA	Manufacture and process development of components used in reagents for sequencing, genotyping and gene expression products used for genetic analysis.
ILLUMINA, INC. 5200 Illumina Way San Diego California 92122 USA	Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression and PCR - products, instruments and software - used for genetic analysis.
ILLUMINA, INC. Hayward 25861 Industrial Blvd. Hayward California 94545 USA	Manufacturing and distribution of instruments used for genetic analysis.
ILLUMINA, INC. 200 Lincoln Centre Drive Foster City California 94404 USA	Design and development of software and assays.
ILLUMINA CAMBRIDGE LIMITED (CAMBRIDGE) 19 Granta Park Great Abington CB21 6DF United Kingdom	Installation, servicing, technical, product and laboratory support services for Sequencing, Genotyping, Gene Expression (products, instruments and software) used for genetic analysis. Purchasing, planning, procurement and supply chain management. Provision of technical services for customers and internal technical staff in use of instruments and systems. Regional regulatory support. Design and development of clinical software and assays for genetic analysis.

Original Registration Date: 2011-01-14

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Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.