

Certificate of Analysis (CofA)

What is a Certificate of Analysis?

A Certificate of Analysis refers to an authenticated document that is issued by Illumina's Quality Assurance Department that ascertains that a product has met its predetermined product release specification(s) and quality.

What information is provided on a Certificate of Analysis?

The document includes the following:

- Company Name/Identifier
- Identification of Kit Product /Product Name
- Kit Part Number/Catalog Number
- Kit Lot Number
- Test Conditions
- Test Parameters
- Specifications or Requirements
- Results (qualitative and/or quantitative)
- Approval Signature and Date
- Relevant document traceability references (e.g. document number, revision, etc.)

Why is a Certificate of Analysis prepared and how is it utilized?

Certificates of Analysis can be used to satisfy qualification and/or acceptance activities (e.g. receiving inspection) by customers that are subject to regulatory or governing body expectations including, but not limited to the following:

- Food and Drug Administration (FDA)
- Clinical Laboratory Improvement Amendments (CLIA)
- International Organization for Standardization (ISO)
- Internal Quality System Procedures

How does a Certificate of Analysis (CofA) compare to a Certificate of Conformance (CofC)?

A Certificate of Conformance is a document certified by a competent authority that the supplied goods or service meets the required specifications but does NOT typically include specific test conditions, test parameters, test specifications/expected results, and final results; also called Certificate of Compliance and Certificate of Conformity.

Who do I contact for support related to Certificates of Analysis?

Contact Technical Support via the following contacts:

7:00am - 5:00pm (PT)
800.809.4566 (North America)
858.202.4566 (Outside)
858.202.4766 (Fax)
TechSupport@illumina.com

How do I find a specific Certificate of Analysis?

You can download current Certificates of Analysis by clicking one of the links listed. The document opens in Acrobat Reader. To save a copy to your computer, click the Save button or press Ctrl+Shift+S.

What file format is the Certificate of Analysis stored as?

Certificates of Analysis are stored as Adobe Acrobat PDF files.

Which Illumina products will have Certificates of Analysis?

Certificates of Analysis shall be established for all *In Vitro* Diagnostic (IVD) kits and Translational Genomic (TG) products for customers on TG supply agreements only.

Why aren't Certificates of Analysis provided for Research Use Only (RUO) products?

Requires kit level-testing with release methods and predetermined acceptance criteria (i.e. release requirements); kit level-testing is not appropriate for products labeled as Research Use Only.

Will I get different CofA's for different lots of reagents that I purchase?

Yes. Certificates of Analysis are available through the Illumina website at www.illumina.com, and are traceable by lot number.