

Atellica® IM Quality Control Material Supplement

Current Revision and Date^a	Rev. 01, 2022-07
Systems	Atellica IM Analyzer

^a A vertical bar in the page margin indicates technical content that differs from the previous version.



Introduction

This Quality Control Material Supplement contains information about Quality Control (QC) materials.

For assay Instructions for Use (IFUs) that indicate the use of commercially available controls, the minimum recommendations are provided in the quality control section of the respective assay IFU.

The table below contains examples of QC materials and is not intended to be all inclusive. Refer to the respective QC manufacturer for platform-specific information. Each laboratory should select QC material that meets their needs.

Assay	Siemens Healthineers REF	QC Manufacturer QC Material Name (REF)
Alpha Fetoprotein (AFP)	10995441 10995442	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Androstenedione (ANDRO)	11200558	Bio-Rad Lyphochek Immunoassay Plus Control, 3 levels (371, 372, 373)
BR 27.29 (BR)	10995478 10995477	Bio-Rad Liquichek Tumor Marker Control, 3 levels (547, 548, 549, 548X)
CA 125II™	10995481 10995482	Bio-Rad InteliQ Tumor Marker Control, 3 levels (12008289, 12008290, 12008291)
CA 15-3™	10995485 10995486	Bio-Rad InteliQ Tumor Marker Control, 3 levels (12008289, 12008290, 12008291)

Assay	Siemens Healthineers [REF]	QC Manufacturer QC Material Name ([REF])
CA 19-9™	10995490 10995489	Bio-Rad InteliQ Tumor Marker Control, 3 levels (12008289, 12008290, 12008291)
Calcitonin (CALCT)	10733004	Bio-Rad Lyphochek Immunoassay Plus Control, 3 levels (371, 372, 373)
Carcinoembryonic Antigen (CEA)	10995523 10995524	Bio-Rad InteliQ Tumor Marker Control, 3 levels (12008289, 12008290, 12008291)
Creatine kinase MB (CKMB)	10995530 10995531	Bio-Rad InteliQ Cardiac Marker Plus LT Control, 3 levels (12009955, 12009956, 12009957)
Cortisol (Cor)	10995538 10995537	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
C-peptide (CpS)	10995541	Bio-Rad InteliQ Specialty Immunoassay Control, 3 levels (12008277, 12008278, 12008279)
Cyclosporine (CsA)	10995548	Bio-Rad Lyphochek Whole Blood Immunosuppressant Controls, 5 levels (274, 275, 276, 277, 278, 279X)
DHEA-SO4 (DHEAS)	10995555	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Digitoxin (Dgtn)	10995554 10995553	Bio-Rad InteliQ Cardiac Marker Plus LT Control, 3 levels (12009955, 12009956, 12009957)
Digoxin (Dig)	10995558 10995557	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Enhanced Estradiol (eE2)	10995561 10995562	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Ferritin (Fer)	10995569 10995568	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Free Beta Human Chorionic Gonadotropin (FBHCG)	10733009 10733010	Bio-Rad Liquichek Maternal Serum 1st Trimester Control, 3 levels (636)
Folate (Fol)	10995572 10995573	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)

Assay	Siemens Healthineers REF	QC Manufacturer QC Material Name (REF)
Free Triiodothyronine (FT3)	10995585 10995584	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Free Thyroxine (FT4)	10995589 10995588	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Follicle Stimulating Hormone (FSH)	10995580 10995581	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Free Prostate-Specific Antigen (fPSA)	10995577	Bio-Rad InteliQ Tumor Marker Control, 3 levels (12008289, 12008290, 12008291)
Homocysteine (HCY)	10995606 10995607	Bio-Rad Liquichek Homocysteine Control, 3 levels (287, 288, 289, 288X)
High-Sensitivity Troponin I (TnIH)	10997840 10997841	Bio-Rad InteliQ Cardiac Marker Plus LT Control, 3 levels (12009955, 12009956, 12009957)
Insulin (IRI)	10995628	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Luteinizing Hormone (LH)	10995635 10995634	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Myoglobin (MYO)	10995649 10995648	Bio-Rad InteliQ Cardiac Marker Plus LT Control, 3 levels (12009955, 12009956, 12009957)
NT-proBNP (PBNP)	11200588 11200589	Bio-Rad InteliQ Cardiac Marker Plus LT Control, 3 levels (12009955, 12009956, 12009957)
Pregnancy-Associated Plasma Protein-A (PAPP-A)	10733019 10733020	Bio-Rad Liquichek Maternal Serum 1st Trimester Control, 3 levels (636)
Progesterone (PRGE)	10995660 10995659	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Prolactin (PRL)	10995656 10995655	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Prostate-Specific Antigen (PSA)	10995662 10995663	Bio-Rad InteliQ Tumor Marker Control, 3 levels (12008289, 12008290, 12008291)
Sex Hormone Binding Globulin (SHBG)	10995672	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)

Assay	Siemens Healthineers [REF]	QC Manufacturer QC Material Name ([REF])
Total hCG (ThCG)	10995690 10995689	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Total IgE (tIgE)	10995615 10995614	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Testosterone II (TSTII)	10995708 10995707	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Thyroglobulin (Tg)	11200450 11200534	Bio-Rad InteliQ Tumor Marker Control, 3 levels (12008289, 12008290, 12008291)
Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)	10995703 10995704	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Total Thyroxine (T4)	10995684 10995685	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Total Triiodothyronine (T3)	10995679 10995678	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Thyroid Uptake (TUp)	10995712 10995711	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)
Vitamin B12 (VB12)	10995714 10995715	Bio-Rad InteliQ Immunoassay Plus Control, 3 levels (12009948, 12009949, 12009950)

Regulatory Information

Product and system availability are subject to local regulatory requirements and, therefore, vary by country. If you have any questions or need additional information, please contact your local technical support provider or distributor.

Technical Assistance

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

For customer support, contact your local technical support provider or distributor.


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Legal Information

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