


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 UKAS MEDICAL 8567 Accredited to ISO 15189:2012	Medical Diagnosis Ltd	
	Issue No: 007 Issue date: 25 August 2021	
	Unit 12 Central Business Centre Great Central Way London NW10 0UR	Contact: Dr George Xynopoulos Tel: +44 (0) 208 45 19 373 Website: http://www.medical-diagnosis.co.uk/
Testing performed at the above address only		

Site activities performed away from the laboratory:

Location details	Site Activity
Unit 12 Central Business Centre Great Central Way London NW10 0UR	Phlebotomy Sample Collection for General Population, Test to Release Day 5, and Day 2 and Day 8.



8567

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Medical Diagnosis Ltd

Issue No: 007 Issue date: 25 August 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<p><u>Biochemistry examination activities for the purposes of clinical diagnosis:</u></p>	<p>Documented in-house Methods and Manufacturer's instructions for analysis using the Roche Cobas e411 for immunoassays as documented in SOP WI-25 Cobas e411 based on Electrochemiluminescence immunoassay (ECLIA)</p>
Blood serum	<p><u>General chemistry including hormones</u></p> <p>Thyroid-stimulating hormone Free thyroxine Free triiodothyronine Estradiol Follicle stimulating hormone Intact hCG + free beta-subunit Luteinizing hormone Progesterone Prolactin Testosterone T4 T3 Folate Vitamin B12 Vitamin D 25-OH SHBG DHEA-S C-Peptide Insulin</p> <p>Immunology tests Anti -TPO Anti-TG</p> <p><u>General chemistry cont'd including hormones</u></p> <p>17-OH Progesterone Free Prostate Specific Antigen Testosterone Free Growth Hormone Insulin-like growth factor-I</p>	
		<p>Documented in-house Methods and Manufacturer's instructions for Chemiluminescence immunoassay using the Snibe Maglumi 2000 plus documented in SOP WI-29 Maglumi 2000 Plus chemiluminescence immunoassay (CLIA)</p>



8567

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Medical Diagnosis Ltd

Issue No: 007 Issue date: 25 August 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in-house Methods and Manufacturer's instructions for Chemiluminescence immunoassay using the Snibe Maglumi 2000 plus documented in SOP WI-29 Maglumi 2000 Plus chemiluminescence immunoassay (CLIA)
Blood serum	<u>General chemistry cont'd including hormones contd</u> Total Prostate Specific Antigen Reverse Triiodothyronine TSH receptor antibodies Thyroid-stimulating hormone Cortisol	
Blood serum	<u>Serology</u> <u>2019-nCoV IgM</u> <u>2019-nCoV IgG</u>	Documented in-house Methods and Manufacturer's instructions for Chemiluminescence immunoassay using the Snibe Maglumi 2000 plus and Maglumi 2000 documented in SOP WI-29 Maglumi 2000 and Maglumi 2000 Plus chemiluminescence immunoassay (CLIA)
	Qualitative determination of hepatitis B surface antigen (HBs Ag)	Documented in-house Methods and Manufacturer's instructions for analysis using the Roche Cobas e411 for immunoassays as documented in SOP WI-25 Cobas e411 Electrochemiluminescence immunoassay (ECLIA)



8567

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Medical Diagnosis Ltd

Issue No: 007 Issue date: 25 August 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p>	<p><u>Serology cont'd.</u></p> <p>Qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 (HIV 1&2 Ab + HIV-1 p24 Ag)</p> <p>Qualitative detection of total antibodies to hepatitis C virus (HCV Ab)</p> <p>Qualitative determination of total antibodies to Treponema pallidum (Syphilis Ab)</p> <p>Qualitative determination of IgG and IgM antibodies to the hepatitis B core antigen (HBc Ab)</p> <p>Quantitative determination of human total antibodies to the hepatitis B surface antigen (HBs Ab)</p> <p>Qualitative determination of total antibodies to HTLV-I/II (HTLV Ab)</p>	<p>Documented in-house Methods and Manufacturer's instructions for analysis using the Roche Cobas e411 for immunoassays as documented in SOP WI-25 Cobas e411 Electrochemiluminescence immunoassay (ECLIA)</p>



8567

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Medical Diagnosis Ltd

Issue No: 007 Issue date: 25 August 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS Whole Blood (EDTA)	<u>Haematology examination activities for the purposes of clinical diagnosis:</u> Full Blood Count analysis: White Blood Cells (WBC) Red Blood Cells (RBC) Platelets (PLT) Hemocrit (HCT) Haemoglobin White Blood Cell (WBC) 5 Differential: neutrophils, lymphocytes, monocytes, eosinophils, basophils	Documented in-house Methods WI-17 Sysmex XT-1800i and Manufacturer's instructions for Sysmex XT-1800i using Impedance and Direct Current (DC) detection method combined with hydrodynamic focusing technology



8567

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Medical Diagnosis Ltd

Issue No: 007 Issue date: 25 August 2021

Testing performed at main address only

HUMAN BODY TISSUES AND FLUIDS

Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab Sampling

Sampling with subsequent testing at a laboratory accredited to ISO 15189:2012 or ISO/IEC 17025:2017 and/or on the DHSC list of approved private providers of COVID-19 testing:

For:

General Population, Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods

Test to Release Day 5
Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods

Day 2 & 8 International Arrival
Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods

Virology examination procedures for the purposes of clinical diagnosis

In house method based on PHE Guidance for COVID-19 Sampling for testing purposes



8567

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Medical Diagnosis Ltd

Issue No: 007 Issue date: 25 August 2021

Testing performed at main address only

Nasopharyngeal Swab - Combined
Nasopharyngeal & Oropharyngeal
(Nose & Throat)

Detection of SARS-CoV-2 virus
RNA (COVID-19) from N
(nucleocapsid) and E (Envelope)
coding regions

Documented in house methods
including DHSC requirements for
Private Providers of Covid-19
testing, to include:

- General population testing
- Test to Release (Day 5)
testing
- Day 2 & Day 8
International Arrival
testing

COVID-19 PCR with Nexor 96
extraction and then:

- DT prime RT and/or
QIAquant with Eurobio kits
(RDRP1/2, N gene)
- CFX96 with Nonacus (N1, E
gene)
- CFX96 with Seegene Kits
(E, RdPR/S, N gene) - TTR
and General Population only

END