


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 6341</p> <p>Accredited to ISO 15189:2012</p>	<p>Almac Diagnostics Services Ltd</p> <p>Issue No: 004 Issue date: 01 August 2021</p>	
	<p>Unit 19 Seagoe Industrial Estate Craigavon Co Armagh Northern Ireland BT63 5QD</p>	<p>Contact: Stewart McWilliams Tel: +44 (0)28 3833 7575 Fax: +44 (0)28 3839 8676 E-Mail: stewart.mcwilliams@almacgroup.com Website: www.almacgroup.com/diagnostics</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	<u>Molecular Biology examination activities for the purpose of clinical trials</u>	Documented in-house procedures in conjunction with manufacturer's instructions:
FFPE	Basophilic and eosinophilic tissue structures	Maunal Haematoxylin & Eosin (H&E) staining, GL.SOP.LAB.181
FFPE	Nucleic acid extraction and quality assurance for downstream genetic analysis	DNA Extraction using DNA Sample Preparation Kit and DNA quantification using Nanodrops 1000 or 8000. Amplifiability assessment performed using TruSeq Custom Amplicon Dx-FFPE Kit and Roche Lightcycler GL.SOP.LAB.470
DNA extracted from FFPE tissue	Testing to identify p53 wild type patients for inclusion in clinical trials	Library preparation using Almac Custom TP53 Oligo Panel Library Verification using Bioanalyser 2100 Normalisation and clean up and dilution using TruSeq Custom Amplicon Kit Dx with bead normalisation Library analysis using MiSeq and: MiSeq Reagent v3 or MiSeq Reagent v2 Nano and accompanying flow cells GL.SOP.LAB.443



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

Almac Diagnostics Ltd

Issue No: 003 Issue date: 28 January 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 AND TISSUES</p> <p>Data derived from primary analysis</p> <p>VCF files generated by Almac TP53 V 2 Analysis Software primary pipeline</p>	<p><u>Molecular Biology examination activities for the purpose of clinical trials</u></p> <p>Determination of Data quality</p> <p>Detection of wildtype sequences, SNV, Deletions and insertions in TP53</p>	<p>Documented in-house procedures in conjunction with manufacturer's instructions:</p> <p>Primary Data Analysis for quality control (Sequencing run QC, Control QC and Test Sample QC) using onboard MiSeq Reporter software and primary in-house pipeline- Almac TP53 v 2 Analysis Software</p> <p>GL.SOP.LAB.503</p> <p>Customer specific secondary data analysis (variant filtering, annotation)</p> <p>Almac TP53 CTA v2 ADX17083 Analysis Software</p> <p>GL.SOP.LAB.502</p>
<p>END</p>		