



Name	: Mr.DUMMY REPORT	Centre Details	: DUMMY GURGAON DUMG
Age	: 45 Yrs Sex: Male	Accession.ID	: OQG2511060958
Collection Date	: 06/Nov/2025 03:17PM	Referred By	: SELF
Received Date	: 06/Nov/2025 03:17PM	Report Date	: 06/Nov/2025 05:29PM
Registration Date	: 06/Nov/2025 03:12PM	Ref.No/TRF.No	: /

DEPARTMENT OF MOLECULAR DIAGNOSTICS-II

ONCQSOL CGP 550+ WITH PD-L1

OncqSol CGP 550+ Next Generation Sequencing

Clinical Indication: Lung Carcinoma
Specimen: Slides from P. Block: 4317/22 (6)
Tumor Content & Cellularity: 40%; Adequate
Site: Left Lung Biopsy

Test Result Summary

POSITIVE Clinically relevant actionable Variant and Fusion detected in this subject
NEGATIVE No clinically relevant Copy Number Variant (CNV) was detected in this subject

Gene	CDS variant details	Amino acid change/ Exon No.	Overall depth/ Mutant Allele Percentage	Variant Classification (AMP/ASCO/CAP)
EGFR	c.2236_2250delGAATTAAGAGAAGCA	p.Glu746_Ala750del/ Exon 19	586x/ 66.38%	Tier; IA FDA Approved Drug Labels: afatinib, amivantamab + lazertinib, acoitinib, erlotinib + ramucirumab, gefitinib, osimertinib, osimertinib + chemotherapy, amivantamab, chemotherapy and datopotamab deruxtecan-dlnk

Fusion Gene	Breakpoint	Total Reads
NAV1::NTRK2	chr1:201821519: chr9:84814045	8002

Multi-gene Biomarker Results:

Gene	CDS variant details	Amino acid change/ Exon No.
Microsatellite Instability (MSI)	High	High Microsatellite Stability detected.
Tumor Mutation Burden (TMB)	10.88 Mutations/Mb (Intermediate)	Moderate response anticipated towards Immuno-Oncology therapy

*Genetic test results are reported based on the recommendations of AMP-ASCO-CAP guidelines. #Correlation of the genetic findings with the clinical condition of the patient is required to arrive at an accurate diagnosis, prognosis or therapeutic decisions

Additional Biomarkers Detected

This section provides information about variants that do not have any therapeutic value. However, these variants may or may not have a likely oncogenic effect.

Gene	CDS details	Amino acid change/ Exon No.	Overall depth/ Mutant Allele Percentage	Locus	Transcript	Variant Effect
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None

Variant Classification as per AMP-ASCO-CAP Guidelines

Variant	A change in a gene. This could be disease causing (pathogenic) or not disease causing (benign).
Tier I: Variants of Strong Clinical Significance	Level A , biomarkers that predict response or resistance to US FDA-approved therapies for a specific type of tumor or have been included in professional guidelines as therapeutic, diagnostic, and/or prognostic biomarkers for specific types of tumors; Level B , biomarkers that predict response or resistance to a therapy based on well- powered studies with consensus from experts in the field or have diagnostic and/or prognostic significance of certain diseases based on well-powered studies with expert consensus.
Tier II: Variants of Potential Clinical Significance	Level C , biomarkers that predict response or resistance to therapies approved by FDA or professional societies for a different tumor type (i.e., off-label use of a drug), serve as inclusion criteria for clinical trials, or have diagnostic and/or prognostic significance based on the results of multiple small studies. Level D , biomarkers that show plausible therapeutic significance based on preclinical studies or may assist disease diagnosis and/or prognosis themselves or along with other biomarkers based on small studies or multiple case reports with no consensus.
Tier III: Variants of unknown clinical significance	Not observed at a significant allele frequency in the general or specific subpopulation or pan cancer or tumor specific variant databases. No convincing published evidence of Cancer Association

MSI	Unstable Loci
MSI - Stable	1-18
Intermediate/ No Call	18-19
MSI - Unstable	>19

TMB	Category	Interpretation
1-5 Mutations/Mb	Low	Unlikely to benefit from Immuno-Oncology therapy.
6-19 Mutations/Mb	Intermediate	Moderate response anticipated towards Immuno-Oncology therapy.
>20 Mutations/Mb	High	Good and significant response expected to Immuno-Oncology therapy

Test Attributes, Methodology:

- This is a Next Generation Sequencing based test which identifies genetic alterations in a comprehensive panel of >500 genes which can impact response to approved therapy for a particular cancer type. Some of the alterations detected may have bearing on prognosis and/or therapeutic options and may provide relevant information that allows doctor to consider various lines of targeted treatment for the patient.
- Sample preparation and Library preparation: DNA isolated from FFPE or any other fresh tumor tissue source was used to perform targeted gene capture using a custom capture kit. The libraries were sequenced to mean >500X coverage on ThermoFisher sequencing platform. The Oncomine™ Comprehensive Assay Plus is a targeted, next-generation sequencing (NGS) assay that provides a comprehensive genomic profiling solution appropriate for formalin-fixed paraffin-embedded (FFPE) tissues. The assay allows concurrent analysis of DNA and RNA to simultaneously detect multiple biomarkers associated with targeted and immune



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checkpoint research, including comprehensive targets that are relevant in cancer, in a single workflow.

- **Bioinformatics Analysis and Reporting:** The sequences obtained are aligned to human reference genome (GRCh37/hg19) and variant analysis is performed using set of Bioinformatics Pipeline. Variant calling, annotation and classification of the variants were done using ion reporter 5.2.0 software. Clinically relevant mutations are annotated using published variants in literature and a set of databases – ClinVar, COSMIC and dbSNP. Common variants are filtered based on allele frequency in 1000 Genome Phase 3, ExAC, EVS, dbSNP147, etc. Non-synonymous variants effect is calculated using multiple algorithms such as PolyPhen-2, SIFT, MutationTaster2, Mutation Assessor and LRT. Silent variations that do not result in any change in amino acid in the coding region are not reported. It enables the identification of SNV, Indels, Gene level copy number variants, TMB score, MSI status, arm level aneuploidy, gene fusions, Homologous recombination deficiency through Genomic instability metric (GIM), Gene LOH for BRCA1/BRCA2 and other HRR genes, full coverage of DNA repair pathways including HRR and MMR Genomic instability metric (GIM) is a novel metric to quantify genomic scars/instability associated with HRD. It is based on genomic segmentation2 using CNV log2 ratios and log odds for SNP allele frequencies, which allows to summarize different unbalanced copy number events across autosomes. It ranges from 0-100, and higher values indicate more genomic instability.
- The performance of the was verified using both commercially sourced reference controls and FFPE samples. Tumor Mutation Burden (TMB) & Microsatellite Instability: study potential response to immunotherapies with measurement of tumor mutational burden (TMB), predisposition to genetic hypermutability by comparing microsatellite instability (MSI) regions and analyse mutational signatures for insights into etiological factors in tumorigenesis.
- This kit enables us to detect Genomic instability matrix (GIM). Genetic Instability Metric (GIM) is a proprietary measurement in Ion Reporter™ software that quantifies genomic scarring associated with Homologous Recombination Deficiency (HRD). The GIM is a numeric value between 0 and 100 that summarizes unbalanced copy number changes using genomic segmentation. GIM values are higher in HRD-positive samples than they are in HRD-negative samples in ovarian cancer (GIM values ≥16). Higher value correlate with the observation of more genomic instability in the sample. The sensitivity of the assays depends on the quality of the sample and tumor content.

Comprehensive Genomic Panel gene list:

CNV gain and Hotspot Genes (n=185)						TMB only genes** (n=89)		
ABCB1	CD79B*	FGF7*	IKBKB	MYCN	PXDNL	STAT5B	A1CF	KRTAP21-1
ABL1	CDK4	FGF9	IL6ST*	MYD88	RAC1	STAT6	ACSM2B	KRTAP6-2
ABL2	CDK6	FGFR1	IL7R	MYO1*	RAF1	TAF1	ADAM18	LRRCT
ACVR1*	CHD4	FGFR2	IRF4*	NFE2L2	RARA	TERT	ANO4	MARCO
AKT1	CSF1R*	FGFR3	IRS4*	NRAS	RET	TGFBR1*	ARMC4	NLRCS
AKT2	CTNNB1*	FGFR4	KDR	NSD2*	RGS7*	TOP1	AURKB	NOL4
AKT3	CTNND2	FLT3	KIT	NTSC2*	RHEB	TPMT	BRINP3	NRXN1
ALK	CUL1*	FLT4	KLF4*	NTRK1	RHOA*	TRRAP*	C6	NYAP2
AR	CYSLTR2*	FOXA1	KLF5	NTRK2	RICTOR	TSHR*	C8A	OR10G8
ARAF	DDR1	FOXL2*	KNSTRN*	NTRK3	RIT1	U2AF1	C8B	OR2G6
ATP1A1*	DDR2	FOXO1*	KRAS	NUP93*	ROS1	USP8	CANX	OR2L13
AURKA	DGCR8*	FYN	MAGOH	PAX5*	RPL10*	WAS*	CASR	OR2L2
AURKC	DROSHA*	GATA2	MAP2K1	PCBP1	RPS6KB1	XPO1	CD163	OR2L8
AXL	E2F1*	GLI1*	MAP2K2*	PDGFRA	RPTOR	YAP1	CNTN6	OR2M3
BCL2	EGFR	GLI3	MAPK1	PDGFRB	SETBP1	YES1	CNTNAP4	OR2T3
BCL2L12	EIF1AX	GNA11*	MAX	PIK3C2B	SF3B1	ZNF217	CNTNAP5	OR2T33
BCL6	EMSY	GNAQ*	MCL1	PIK3CA	SDX1*	ZNF429	COL11A1	OR2T4
BCR*	EPAS1*	GNAS	MDM2	PIK3CB	SDX2*		DCAF4L2	OR2W3
BMP5*	ERBB2	H1-4*	MDM4	PIK3CD*	SLCO1B3		DCDC1	OR4A15
BRAF	ERBB3	H2BC5*	MECOM	PIK3CG*	SMC1A		GALNT17	OR4C15
BTX*	ERBB4	H3-3A	MED12*	PIK3R2	SMO		GPR158	OR4C6
CACNA1D*	ESR1	H3-3B	MEF2B	PIK3R1	SNCAIP*		GRID2	OR4M1
CARD11	EZH2	H3C2*	MET	PLCG1	SOS1*		HCN1	OR4M2
CBCL	FAM135B	HIF1A*	MTF	PPP2R1A	SOX2*		HLA-C	OR5D18
CCND1	FGF19	HRAS	MPL	PPP6C	SPOP		KCND2	OR5F1
CCND2	FGF23	IDH1*	MTOR	PRKACA	SRC		KCNH7	OR5L1
CCND3	FGF3	IDH2	MYC	PTPN11	SRSF2*		KCNJ5	OR5L2
CCNE1	FGF4	IGF1R	MYCL	PTPRD*	STAT3		KEL	OR6F1
							KIR3DL1	OR8H2
								OR8I2
								ZNF536



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CDS genes (n=227)								Gene Fusions (inter- and intra-genic) (n=49)	
ABRAXAS1	CASP8	DICER1	FBXW7	MAP3K4	PDIA3	RB1	TAP1	AKT1	NOTCH2
ACVR1B	CBFB	DNMT3A	FUBP1	MAPK8	PGD	RBM10	TAP2	AKT2	NOTCH3
ACVR2A	CD274	DOCK3	GATA3	MEN1	PHF6	RECQL4	TBX3	AKT3	NRG1
ADAMTS12	CD276	DPYD	GNA13	MGA	PIK3R1	RNASEH2A	TCF7L2	ALK	NTRK1
ADAMTS2	CDC73	DSC1	GPS2	MLH1	PMS1	RNASEH2B	TET2	AR	NTRK2
AMER1	CDH1	DSC3	HDAC2	MLH3	PMS2	RNASEH2C	TGFBR2	BRAF	NTRK3
APC	CDH10	ELF3	HDAC9	MRE11	PCOL1	RNF43	TMEIM132D*	BRCA1	NUMT1
ARHGAP35	CDK12*	ENO1	HLA-A	MSH2	PCOL1	RPA1	TNFAIP3	CDKN2A	PIK3CA
ARID1A	CDKN1A	EP300	HLA-B	MSH3	POT1	RPL22*	TNFRSF14	EGFR	PIK3CB
ARID1B	CDKN1B	EPCAM	HNF1A	MSH6	PPM1D	RPL5*	TP53	ERBB2	PPARG
ARID2	CDKN2A	EPHA2	ID3*	MTAP	PPP2R2A	RUNX1	TP63	ERBB4	PRKACA
ARID5B	CDKN2B	ERAP1	INPP4B	MTUS2*	PRDM1	RUNX1T1	TPP2	ERG	PRKACB
ASXL1	CDKN2C	ERAP2	JAK1	MUTYH	PRDM9	SDHA	TSC1	ESR1	RAF1
ASXL2	CHEK1*	ERCC2	JAK2	NBN	PRKAR1A	SDHB	TSC2	ETV1	RARA
ATM*	CHEK2*	ERCC4	JAK3	NCOR1	PSMB10*	SDHC	UGT1A1*	ETV4	RELA
ATR	CIC	ERCC5*	KDM5C	NF1	PSMB8*	SDHD	USP9X	ETV5	RET
ATRX	CIITA*	ERRF1	KDM6A	NF2	PSMB9*	SETD2	VHL	FGFR1	ROS1
AXIN1	CREBBP	ETV6	KEAP1	NOTCH1	PTCH1	SLX4	WT1	FGFR2	RSPD2
AXIN2	CSMD3	FANCA	KLHL13*	NOTCH2	PTEN	SMAD2	XRCC2	FGFR3	RSPD3
B2M	CTCF	FANCC	KMT2A	NOTCH3	PTPR	SMAD4	XRCC3	MAP3K8	STAT6
BAP1	CTLA4	FANCD2	KMT2B	NOTCH4	RAD50	SMARCA4	ZBTB20*	MET	TERT
BARID1*	CUL3	FANCE	KMT2C	PALB2*	RAD51	SMARCB1	ZFH3	MYB	TFEB
BCOR	CUL4A	FANCF	KMT2D	PARP1	RAD51B*	SOC1	ZMYM3	MYBL1	YAP1
BLM	CUL4B	FANCG	LARP4B	PARP2	RAD51C*	SOX9	ZRSR2		
BMPR2	CYLD	FANCI	LATS1	PARP3	RAD51D*	SPEN			
BRCA1*	CYP2C9	FANCL*	LATS2	PARP4	RAD52	STAG2			
BRCA2*	CYP2D6*	FANCM	MAP2K4	PBRM1	RAD54L*	STAT1			
BRIP1*	DAXX	FAS*	MAP2K7	PDCD1	RASA1	STK11			
CALR*	DDX3X	FAT1	MAP3K1	PDCD1LG2	RASA2	SUFU			

Disclaimer:

DNA studies do not constitute a definitive test for the selected condition(s) in all individuals. It should be realized that there are possible sources of error. Errors can result from trace contamination, rare technical errors, rare genetic variants that interfere with analysis, recent scientific developments, and alternative classification systems. This test should be one of the many aspects used by the healthcare provider to help with a diagnosis and treatment plan. The contents of this test should be carefully assessed by the treating physician and further interpreted along with clinical, histopathological findings, contraindications and guidelines before deciding the course of therapy. Most recent block is recommended for testing as the mutation profile may change in response to treatment and hence differ at different sampling points. Certain genes may not be covered completely, and few mutations could be missed. A negative result cannot rule out the possibility that the tested tumor sample carries mutations not previously associated with cancer and hence not included in the panel. The accuracy and completeness may vary due to variable information available in different databases. The classification of variants of unknown significance can change over time. Synonymous mutations were not considered while preparing this report. The mutations have not been confirmed using Sanger sequencing and/or alternate technologies. To rule out germ line mutations i.e. variant with variant allele frequency at nearly 50% or 100%, whole blood sample is recommended to process along with tissue sample. No other variant that warrants to be pathogenic was detected. Variations with high minor allele frequencies which are benign/likely benign will be given upon request. Due to poor quality of FFPE DNA, indeterminate result due to low gene coverage or low variant depth cannot be ruled out. The sensitivity of the assays depends on the quality of the block, and tumor content

References:

- Li, Marilyn M., et al. "Standards and guidelines for the interpretation and reporting of sequence variants in cancer: a joint consensus recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists." The Journal of Molecular Diagnostics (2017) 19(1): 4-23. PMID: 27993330.
- Richards, Sue, et al. "Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology." Genetics in Medicine (2015) 17(5): 405. PMID: 25741868.
- Forbes, Simon A., et al. "COSMIC: somatic cancer genetics at high-resolution." Nucleic Acids Research (2016) 45(D1): D777-D783. PMID: 27899578.
- Exome Aggregation Consortium et al. "Analysis of Protein-Coding Genetic Variation in 60,706 Humans." Nature (2016) 536(7616): 285-291. PMID: 27535533.
- The 1000 Genomes Project Consortium. "A Global Reference for Human Genetic Variation." Nature (2015) 526(7571): 68-74. PMID: 26432245.



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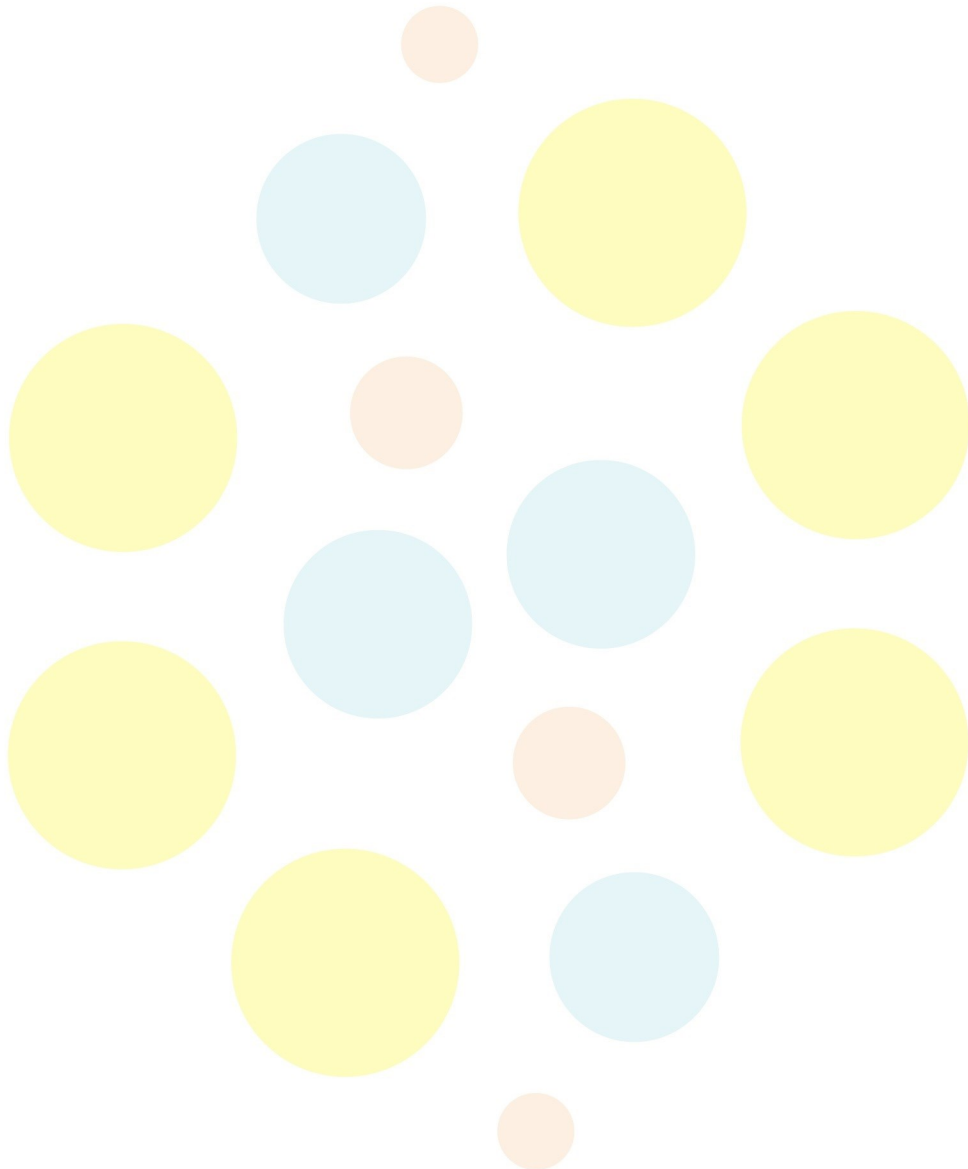


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Note: The performance of this Test has been evaluated at Oncquest Laboratories Ltd.




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DEPARTMENT OF IMMUNOHISTOCHEMISTRY

ONCQSOL CGP 550+ WITH PD-L1

PDL1 (22C3) IHC by Dako

FFPE (Tissue) / FFPE Tissue Block

LAB. NO. : II xxxxxx /25

CLINICAL DETAILS :

XXXXXX

SITE: XXXXXX

SPECIMEN DETAILS :

Received XXXXX paraffin block labeled as XXXXX for IHC.

Adequate Tumor Cells (≥ 100 cells) present : Yes/No

TEST	SCORE
PD-L1 22C3 (DAKO)	Tumor proportion score (TPS) : XXXXX % Combined positive score (CPS) : XXXXX

IHC INTERPRETATION:

Scoring of PD-L1 is tumor site specific.

Staining can be present in both immune cell and tumor cell components.

Tumor cells : Any amount of partial or complete membrane staining is evaluated. Cytoplasmic staining is not included.

Immune cells : Both membrane or cytoplasmic staining of inflammatory cells (lymphocytes or macrophages) is counted.

Results are reported as TPS (Tumor proportion score) or CPS (Combined positive score) -

- TPS (Tumor proportion score) : Percentage of viable tumor cells showing partial or complete membrane staining of any intensity relative to all viable tumor cells present in the sample

- CPS (Combined positive score) : Number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total viable tumor cells, multiplied by 100.

Clinical Utility –

- Non Small Cell Lung Carcinoma (NSCLC).
- Gastric or Gastroesophageal junction adenocarcinoma
- Cervical carcinoma



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DEPARTMENT OF IMMUNOHISTOCHEMISTRY

ONCQSOL CGP 550+ WITH PD-L1

- Urothelial carcinoma
- Head and neck, squamous cell carcinoma (HNSCC).
- Triple Negative Breast Cancer (TNBC)

Non small cell lung carcinoma TPS divided into 3 groups: TPS< 1%: no PD-L1 expression TPS 1-49%: PD-L1 expression TPS≥50%: high PD-L1 expression	Head and neck squamous cell carcinoma (HNSCC) CPS divided into 3 groups: CPS<1: no PD-L1 expression CPS≥1: PD-L1 expression CPS≥20: PD-L1 expression
Cervical carcinoma CPS divided into 2 groups: CPS<1: no PD-L1 expression CPS≥1: PD-L1 expression	Gastric/ gastroesophageal junction adenocarcinoma CPS divided into 2 groups: CPS<1: no PD-L1 expression CPS≥1: PD-L1 expression
Urothelial carcinoma CPS divided into 2 groups: CPS<10: no PD-L1 expression CPS≥10: PD-L1 expression	Triple negative breast cancer (TNBC) Urothelial carcinoma CPS divided into 2 groups: CPS<10: no PD-L1 expression CPS≥10: PD-L1 expression

Note –

- Fixation : This test has been validated for non-decalcified paraffin embedded tissue specimens fixed in 10% neutral buffered formalin.
- This assay has not been validated on tissues subjected to the decalcification process and/ or use of alternative fixatives for bone/ bone marrow specimen or cell blocks.
- The impression is based on the material submitted and is not a complete surgical pathology report
- False negative IHC results due to inadequate fixation of the material sent for evaluation cannot be excluded.

- All positive and negative controls show expected reactivity.
- Test performed using DAKO Autostainer and detection system s Polymer HRP.

*** End Of Report ***

Disclaimer: All Results released pertain to the specimen submitted to the lab 1. Test results are dependent on the quality of the sample received by the lab 2. Tests are performed as per schedule given in the test listing and in any unforeseen circumstances, report delivery may be delayed 3. Test results may show interlaboratory variations 4. All dispute and claims are subjected to local jurisdiction only. Clinical correlation advised. 5. Test results are not valid for medico legal purposes 6. For all queries, feedbacks, suggestions, and complaints, please contact customer care support +0124 665 0000



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