



Certificate of Compliance

We hereby declare that the technical file of product complied with the requirements of In Vitro Diagnostic Medical Devices Regulation (IVDR) 2017/746

Applicants

Name : PATHNSITU BIOTECHNOLOGIS PVT LTD

Address : PS HEIGHTS, PLOT# A-28/1/11B/B, ROAD# 15, IDA NACHARAM,
HYDERABAD 500076, TELANGANA, INDIA

Product : "PRIMARY ANTIBODIES FOR IMMUNOHISTOCHEMISTRY (IHC), HRP/DAB
DETECTION SYSTEM, SPECIAL STAINS, ANCILLARIES, DENATURATION &
HYBRIDISATION SYSTEM AND HISTOLOGY INSTRUMENTS"
AS PER ANNEXURE

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the In Vitro Diagnostic Medical Devices Regulation (IVDR) 2017/746.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.

1. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
2. The certificate validity is conditioned by positive results or surveillance audits.
3. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
4. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Certificate No. US-PTGS-26-063361

To verify this certificate please visit at www.uscertifications.uk

Date of Certification

1st Surveillance Due

2nd Surveillance Due

Certificate Expiry (Subject to the company maintaining its system
To the required standard)

06TH JAN 2026

05TH JAN 2027

05TH JAN 2028

05TH JAN 2029




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1. Antibodies					
S.NO	Product Name (Clone)	S.NO	Product Name (Clone)	S.NO	Product Name (Clone)
1	AFP (EP209)	41	Kappa light chain (EP171)	81	Cytokeratin HMW (34be12)
2	Androgen Receptor (EP120)	42	Lambda light chain (EP172)	82	EpCAM (BER-EP4)
3	Alpha Actin (EP188)	43	Mammaglobin (EP249)	83	Ki67 (GM010)
4	BCL2 (EP36)	44	MART 1 (EP43)	84	Melanosome (HMB45)
5	Beta Catenin (EP35)	45	MCM2 (EP40)	85	MLH1 (GM011)
6	CA125 (EP48)	46	Mesothelin (EP140)	86	p53 (BP-53-12)
7	Caldesmon (EP19)	47	MSH2 (RED2)	87	Vimentin (V9)
8	Calponin 1 (EP63)	48	MSH6 (EP49)	88	p63 (4A4)
9	Cathepsin D (EP81)	49	Myeloperoxidase (EP151)	89	Cytokeratin 5/6 (EP24 & EP67)
10	CD1a (EP80)	50	MyoD1 (EP212)	90	Epithelial Membrane Antigen (EMA) (E29)
11	CD4 (EP204)	51	Napsin A (EP205)	91	CD19 (EP169)
12	CD5 (EP77)	52	Neurofilament (EP79)	92	TdT (EP266)
13	CD7 (EP132)	53	OCT4 (EP143)	93	CD15 (BRA-4F1)
14	CD138 (EP201)	54	p120 Catenin (EP66)	94	MUM1 (EP190)
15	CD23 (EP75)	55	PAX5 (EP156)	95	CD68 (KP1)
16	CD31 (EP78)	56	PCNA (EP91)	96	HepPar1 (OCH1E5)
17	CD34 (EP88)	57	PLAP (EP194)	97	Desmin (GM007)
18	CD45 (EP68)	58	PMS2 (EP51)	98	Cytokeratin 14 (LL002)
19	CD63 (EP211)	59	Progesterone Receptor (EP2)	99	CD45RB (2B11+PD7/26)
20	CD74 (EP167)	60	PSA (EP109)	100	Inhibin Alpha (R1)
21	CD79a (EP82)	61	S100 Beta (EP32)	101	Synaptophysin (EP158)
22	CD99 (EP8)	62	SOX2 (EP103)	102	MART-1 / Melan A (A103)
23	CDX2 (EP25)	63	Survivin (EP119)	103	CD38 (EP135)
24	CEA (EP216)	64	Thyroglobulin (EP250)	104	Calretinin (Polyclonal)
25	Chromogranin A (EP38)	65	Vimentin (EP21)	105	SOX10 (EP268)
26	Cytokeratin 5/14 (EP24 & EP61)	66	Wilms Tumor 1 (EP122)	106	MUC4 (EP256)
27	Cytokeratin 8/18 (EP17 & EP30)	67	SMA (Smooth Muscle Actin) (1A4)	107	Von willebrand factor (Polyclonal)
28	CD117/c-kit (EP10)	68	AMACR (P504S) (13H4)	108	Cytokeratin 19 (EP72)
29	c-Myc (EP121)	69	CD20 (L26)	109	Glut 1 (EP141)
30	Cyclin D1 (EP12)	70	CD30 (BerH2)	110	Human Placental Lactogen (EP241)
31	Cytokeratin 20) (EP23)	71	CD31 (GM006)	111	CD21 (EP64)
32	Cytokeratin 7 (EP16)	72	CD34 (Qbend10)	112	CD2 (EP222)
33	E-Cadherin (EP6)	73	CD45RO (UCHL1)	113	H.pylori (Polyclonal)
34	EGFR (EP22)	74	CD56 (123C3)	114	C4D (C4D204)
35	Estrogen Receptor (EP1)	75	CEA (COL-1)	115	Prostatic Acid Phosphatase (EP53)
36	ERG (EP111)	76	Chromogranin A (Polyclonal)	116	CD8a (C8/468)
37	GCDFP15 (EP95)	77	CD117/c-kit (Polyclonal)	117	MUC1 (EP85)
38	GFAP (EP13)	78	Cytokeratin Pan (AE1/AE3)	118	CD43 (DF-T1)
39	HER2/ERBB2 (EP3)	79	Cytokeratin 20 (Ks20.8)	119	ALK (1A4)
40	Insulin (EP125)	80	Cytokeratin 7 (OVTL12/30)	120	CD3 (Polyclonal)



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S.NO	Product Name (Clone)	S.NO	Product Name (Clone)	S.NO	Product Name (Clone)
121	CD57 (NK1)	161	C4D (EP272)	201	Annexin VII (EP367)
122	TTF1 (EP229)	162	LH alpha (LHa/756)	202	CD209 (C209/1781)
123	Glypican 3 (1G12+GPC3/863)	163	TSH (EP254)	203	Serum Amyloid A (EP335)
124	PSMA (EP192)	164	TFE3 (EP285)	204	CD95 (EP208)
125	Myogenin (EP162)	165	IMP3 (EP286)	205	COL1A1 (EP236)
126	BCL6 (EP278)	166	Clusterin (EP181)	206	FOXP3 (EP340)
127	Glycophorin A (EP213)	167	CD8a (EP334)	207	Geminin (EP355)
128	CD15 (EP273)	168	ALK (EP302)	208	GATA3 (EP368)
129	Lysozyme (EP134)	169	NSE gamma (ENO2/1462)	209	MCM6 (EP375)
130	Myoglobin (EP87)	170	NKX3.1 (EP356)	210	Langerin (EP349)
131	Cyclin E1 (EP126)	171	SALL4 (EP299)	211	PAX8 (EP331)
132	TLE1 (1F5)	172	CD163 (EP324)	212	HSP70 (EP377)
133	COX2 (EP293)	173	ATRX (D5)	213	Alpha-1-Antichymotrysin (EP384)
134	PGP9.5 (Polyclonal)	174	Arginase 1 (Arg1/1125+Arg1/1126)	214	CD248 (EP383)
135	PsAP (PASE/4LJ)	175	Podoplanin (D2-40)	215	MMP7 (EP388)
136	Factor XIII A (EP292)	176	CDK4 (EP180)	216	GRIA2 (EP387)
137	Cytokeratin 10 (EP97)	177	MUC5AC (CLH2)	217	Nucleophosmin (28M1)
138	Cytokeratin 13 (EP69)	178	Parathyroid Hormone (PTH/911)	218	Protein (EP381)
139	CD105 (EP274)	179	CD35 (EP197)	219	CD205 (EP176)
140	MUC1 (GP1.4+E29)	180	ALDH1A1 (EP168)	220	Granzyme B (EP230)
141	PAX2 (EP235)	181	Histone H3 Phospho (pT3) (EP233)	221	CD44 (HCAM/918)
142	FSH (EP257)	182	Transcription Factor PU.1 (EP18)	222	Olig2 (EP112)
143	Growth Hormone (EP267)	183	SATB2 (EP281)	223	SOX11 (CLO142)
144	Prolactin (EP193)	184	DOG1 (EP332)	224	Annexin A1 (BSB-95)
145	MUC2 (EP187)	185	MCM5 (EP84)	225	EpCAM (MOC31)
146	NKX2.2 (NX2/294)	186	OCT2 (EP284)	226	Fascin 1 (SPM133)
147	COX2 (SP21)	187	FOXA1 (EP277)	227	TRIM29 (TRIM29/1041)
148	PD1 (EP239)	188	FOXP1 (EP137)	228	Collagen IV (CO4P)
149	GATA3 (L50-823)	189	CD41 (EP178)	229	Cytokeratin 18 (EP30)
150	Keratin (CAM5.2)	190	HLA-DRB1 (EP191)	230	Myelin basic protein (EP207)
151	INI1 (25)	191	H.pylori (EP279)	231	SOX9 (EP317)
152	ACTH (AH26+57)	192	Myosin Heavy Chain (EP166)	232	CD90 (EP56)
153	CA19.9 (121SLE)	193	CPS1 (EP265)	233	Perforin 1 (PRF1/2470)
154	PD1 (PDCD1/922)	194	Myosin Light Chain (EP99)	234	p16 INK4a (JC8)
155	IDH1 (IDH1/1152)	195	KIM1 (EP309)	235	CD30 (TRA30P)
156	Ki67 (MIB1)	196	RRM1 (EP242)	236	Topoisomerase II alpha (TI2aP)
157	IgG4 (EP138)	197	MDR1 (EP271)	237	Beta hCG (CGP)
158	Uroplankin III (EP321)	198	CD103 (EP206)	238	P40 (delta NPP)
159	TNF Alpha (TNF1172)	199	STAT6 (EP325)	239	CD10 (MMEP)
160	AFP (Polyclonal)	200	MDM2 (D7)	240	NeuN (PFOX3)



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241	PD-L1 (RM320)	277	EBV LMP 1 (3H2104,a,b,c)	312	CD99 (MIC2P)
242	Ki67 (PRM113)	278	H-Caldesmon (ZM79)	313	CA125 (M16P)
243	P63 (PRM114)	279	BRAF (PRM130)	314	Annexin A1 (EP433)
244	P40 (PRM115)	280	Beta hCG (PRM131)	315	CD79a (MB1P)
245	HER2 (PRM116)	281	ROS1 (EP282)	316	CD35 (KNP)
246	CD117/c-kit (PRM117)	282	L1CAM (EP411)	317	SALL4 (ZPSP)
247	CD8a (PRM118)	283	Carbonic Anhydrase IX (EP161)	318	Caldesmon (PRM134)
248	MSH3 (PRM119)	284	LI-Cadherin (EP86)	319	p21 (CIP1P)
249	ZAP70 (PRM120)	285	Wilms Tumor 1 (GUDP)	320	TCL1 (EP105)
250	p16 INK4a (PRM121)	286	PAX2 (FSGSP)	321	Cytokeratin HMW (K903P)
251	Progesterone Receptor (PRM122)	287	TdT (DNTP)	322	Progesterone Receptor (PGRP)
252	PMS2 (MMRP)	288	Calcitonin (PCTP)	323	Estrogen Receptor (ORAP)
253	CD56 (PRM123)	289	CD138 (SDCP)	324	p63 (KETP)
254	Napsin A (PRM124)	290	Muscle Actin (HUC1-1)	325	PAX8 (PBGp)
255	BRAF-V600E (RM8)	291	Cytokeratin 5/6 (EBS1P)	326	Podoplanin (T1AP)
256	BOB1 (PRM126)	292	Cytokeratin Pan (EHKP)	327	CD38 (PRM135)
257	Thyroid Peroxidase (PRM127)	293	Cytokeratin 17 (EP98)	328	CD23 (FCEP)
258	MyoD1 (HLHTP)	294	CD13 (EP117)	329	SDHB (PGL4P)
259	CD30 (PRM128)	295	HIF1 Alpha (EP118)	330	PSA (APSP)
260	P53 (PRM129)	296	Topoisomerase II alpha (PRM125)	331	ACE2 (PDAP)
261	CD20 (BCAP)	297	P53 (DO-7)	332	CD21 (CR2P)
262	DOG1 (ANO1P)	298	ATRX (XH2P)	333	Cytokeratin 14 (NJFP)
263	E-cadherin (CDCAP)	299	Beta hCG (CGBP)	334	EGFR (HERP)
264	EpCAM (TMGP)	300	Uroplakin III (P35P)	335	CD10 (C6D1)
265	ERG (ETSP)	301	Somatostatin (SRIP)	336	MUC1 (PEMP)
266	SOX10 (SRYP)	302	Cyclin D1 (PRM132)	337	INSM1 (IA1P)
267	Synaptophysin (SYPP)	303	CD15 (MMA)	338	Thrombomodulin (ZM105)
268	TTF1 (HBPP)	304	BRG1 (SNFP)	339	CTLA4 (GSEP)
269	CDX2 (TSGP)	305	PAX8 (PRM133)	340	CD11c (EP157)
270	Villin (ACBP)	306	PRAME (EP461)	341	SF1 (BBP)
271	PMEL17 (GP100P)	307	OCT3/4 (OTFP)	342	AMACR (P504S) (BOFAP)
272	Myogenin (RPM DP)	308	HER2 (NGLP)	343	Galectin 3 (EP412)
273	Cytokeratin 8 (IFGP)	309	CD4 (TYP)	344	CD10 (NEPP)
274	Cytokeratin 8/18 (IFGFP)	310	Mammaglobin (SGAP)	345	MSH6 (GTBP)
275	CD3 (TCRP)	311	Lambda Light Chain (MCGP)	346	CD5 (LEU1P)
276	CD7 (LEU9P)				

2. Detection Kits

1	PolyExcel HRP/DAB Detetction System - TwoStep
2	PolyExcel HRP/DAB Detetction System - One Step
3	Detection Combo
4	Detection Kit core
5	Detection Combo - D
6	Detection Combo Kit pro
7	Detection Kit Pro core



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3. Special Stains	
Catalogue	Product Name
SSP001	PAP (Papanicolaou) Stain - Modified Mayer's Hematoxylin
SSP002	Congo Red Stain
SSP003	Periodic Acid - Schiff (PAS) Stain
SSP005	PAP (Papanicolaou) Stain - Harris Hematoxylin
SSP006	PAS-Diastase (PAD) Stain
SSP007	Alcian Blue Stain
SSP008	Alcian Blue PAS (ABPAS) Stain
SSP009	Masson's Trichrome Stain
SSP010	Mucicarmine Stain
SSP011	Grocott's Methenamine Silver (GMS) Stain
SSP012	Acid - Fast Bacteria Stain (Green Counterstain)
SSP013	Reticulin Stain
SSP014	Warthin Starry Stain
SSP015	Oil Red O Stain
SSP016	Papanicolaou (PAP-NA) Stain
SSP017-NA	Acid - Fast Bacteria (AFB-NA) Stain (Green Counterstain)
SSP018-NA	Masson's Trichrome (NA) Stain
SSP019-NA	Congo Red (NA) Stain
SSP020	Perls' Stain
SSP021	Verhoeff-Van Gieson (VVG) Stain
SSP022	Jones Methenamine Silver (JMS) Stain
SSP023	Von Kossa Stain
SSP024	Verhoeff-Van Gieson (VVG-NA) Stain
SSP025	Moval's Pentachrome Stain
SSP026	Masson Fontana Stain
SSP027	Melanin Bleach Stain
4. Ancillaries	
Catalogue	Product Name
PS001	Stunn DAB Substrate Buffer & Chromogen Kit
PS005	PAP PEN
PS006	ImmunoWash Buffer (25X)
PS007	Citrate Buffer (50X)
PS008	EDTA Buffer (50X)
PS009	Tris EDTA Buffer (50X)
PS010	Primary Antibody Diluent
PS011	Microscopic Slides (Positively Charged) (Yellow, Pink, Green, Blue and White)
PS014	Mayer's Hematoxylin
PS015	Protein Block
PS016	UNISpread Microscope slides (Positively charged - Hydrophilic)
PS017	Enhanced Primary Antibody Diluent
PS019	Enhanced Citrate Buffer (50X)
PS020	Modified Mayer's Hematoxylin
PS021	Harris Hematoxylin
PS026	Enrich Primary Antibody Diluent
PS027	Peroxidase Quencher
PS028	Phosphate Buffered Saline (10X)
PS029	Eosin Y Stock Solution
PS030	Bluing Solution
SS001	Orange G6 (OG-6)
SS002	EA 50
SS003	Schiff's reagent
SS004	Diastase Solution (for PAS)
SS005	Alcian Blue Solution
PS7105	Microscopic Single Frosted Slides
PS7107	Microscopic Double Frosted Slides
FFG01-04	Fast Freez Cryozel (Clear, Blue, Green, Yellow)
PS7101	Microscopic Slides Plain
PS7109	Coloured Microscopic Slides (Yellow, Pink, Green, Blue and White)



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5. Instruments

Product Name	Model
Flexigross Smart Generation Grossing Station	PFGS-3(3Feet), PFGS-4(4Feet),PFGS-5(5Feet),PFGS-6(6Feet),PFGS-7(7Feet),PFGS-8(8Feet),PFGS-9(9Feet)
Grossing Station	PFGS-3(3Feet), PFGS-4(4Feet),PFGS-5(5Feet),PFGS-6(6Feet),PFGS-7(7Feet),PFGS-8(8Feet),PFGS-9(9Feet)
Vacuum Tissue Processor	TP100, TP200, TP300
Embedding Center	PS-EC
Cryo Console	PS-CC
Thermol Console	PS-TC
Microtome- Manual	PS543R
Microtome- semi automated	PS544
Microtome- fully automated	PS553AT
Slide Dryer	SD2, SD3
Water Bath	PS-WB2
Flotation bath	PS-FBB
ChromePath - Automated H&E and PAP Stainer	PS-CP5
Denaturation & Hybridization System	PSH12
Fully Automated Slide Stainer	Caliber30
Multi Epitope Retrieval System	MERS i




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