



International Certifications

Certificate of Conformity



Manufacturer

PATHNSITU BIOTECHNOLOGIES PRIVATE LIMITED

PS HEIGHTS, PLOT NO. A-28/1/11B/B, ROAD NO. 15/2, IDA NACHARAM,
HYDERABAD, TELANGANA - 500076, INDIA.

Product

"Primary Antibodies for Immunohistochemistry, HRP/DAB Detection System,
Special Stains, Ancillaries, Denaturation & Hybridization System and Histopathology Instruments"

Product list as per Annex 1

Issued in Compliance with the applicable Directive No. (IVDR) 2017/746 of the European parliament and of the council on In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746.

This is to certify that the technical documentation and test results as required for the device has been reviewed and found to comply with the requirements and the relevant harmonized European standards: EN ISO 14971:2021, ISO 9001:2015, ISO 13485:2016, EN 15223-1:2021, EN ISO 18113-2:2022, EN 61010-2-101:2018, EN 61326-2-2:2021

Any change in the design of the Medical Device shall be immediately reported to EC International Certifications in order to examine validity of this certificate.

Certificate No: ECIC/IVDR/99-22
Initial Certificate Issue Date: December 05, 2019
Certificate Re-Issue Date: July 11, 2023
Certificate Expiry Date: December 04, 2025



Head of Certification

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Annex 1 to Certificate No. - ECIC/IVDR/99-22

1. Primary Antibodies for Immunohistochemistry Rabbit (Monoclonal & Polyclonal) & Mouse (Monoclonal)

Sr. No	Product Name	Sr. No	Product Name	Sr. No	Product Name
1	AFP (EP209)	29	Cytokeratin 8 & Cytokeratin 18 (EP17/EP30)	57	PAX-5 (EP156)
2	Androgen Receptor (EP120)	30	CD117/c-kit (EP10)	58	PCNA (EP91)
3	Alpha-Actin (Smooth muscle) (EP188)	31	c-Myc (EP121)	59	PLAP (EP194)
4	BCL-2 (EP36)	32	Cyclin D1 (EP12)	60	PMS2 (EP51)
5	Beta Catenin (EP35)	33	Cytokeratin 20 (EP23)	61	Progesterone Receptor (EP2)
6	Ca125 (EP48)	34	Cytokeratin 7 (EP16)	62	Prostate-Specific Antigen (PSA) (EP109)
7	Calcitonin (EP92)	35	E-Cadherin (EP6)	63	S100 Beta (EP32)
8	Caldesmon (EP19)	36	EGFR (EP22)	64	SOX2 (EP103)
9	Calponin 1 (EP63)	37	Estrogen Receptor (EP1)	65	Survivin (EP119)
10	Cathepsin-D (EP81)	38	ERG (EP111)	66	Thyroglobulin (EP250)
11	CD1a (EP80)	39	GCDFP-15 (EP95)	67	Vimentin (EP21)
12	CD3 (EP41)	40	GFAP (EP13)	68	Wilms' Tumor 1 ((EP122)
13	CD4 (EP204)	41	HER2/ErbB2 (EP3)	69	Actin-Smooth Muscle (1A4)
14	CD5 (EP77)	42	Insulin (EP125)	70	AMACR (P504S) (13H4)
15	CD7 (EP132)	43	Kappa light chain (EP171)	71	CD20(L26) (L26)
16	CD138 (EP201)	44	Lambda light chain (EP172)	72	CD30 (Ber-H2)
17	CD23 (EP75)	45	Mammaglobin (EP249)	73	CD31 (PECAM-1) (GM006)
18	CD31 (EP78)	46	MART-1 (EP43)	74	CD34 (Qbend10)
19	CD34 (EP88)	47	MCM2 (EP40)	75	CD45RO (UCHL-1)
20	CD45 (EP68)	48	Mesothelin (EP140)	76	CD56 (123C3)
21	CD63 (EP211)	49	MSH2 (RED2)	77	CEA (COL-1)
22	CD74 (EP167)	50	MSH6 (EP49)	78	Chromogranin-A (Polyclonal)
23	CD79a (EP82)	51	Myeloperoxidase (EP151)	79	CD117 (Polyclonal)
24	CD99 (EP8)	52	MyoD1 (EP212)	80	CKAE1/AE3 (AE1/AE3)
25	CDX2 (EP25)	53	Napsin-A (EP205)	81	Cytokeratin 20 (Ks20.8)
26	CEA (EP216)	54	Neurofilament (EP79)	82	Cytokeratin 7 (OV-TL 12/30)
27	Chromogranin-A (EP38)	55	Oct-4 (EP143)	83	Cytokeratin HMW (34bE12)
28	CK5 & CK14 (EP24/EP30)	56	p120 Catenin (EP66)	84	Ep CAM / Epithelial Specific Antigen (Ber-EP4)



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1. Primary Antibodies for Immunohistochemistry Rabbit (Monoclonal & Polyclonal) & Mouse (Monoclonal)

Sr. No.	Product Name	Sr. No.	Product Name	Sr. No.	Product Name
85	Melanosome (HMB45)	113	CD21 (EP64)	141	Cytokeratin 13 (EP69)
86	Ki-67 (GM010)	114	CD2 (EP222)	142	CD105 (EP274)
87	MLH1 (GM011)	115	H. pylori (Polyclonal)	143	MUC1 (GP1.4+E29)
88	P53 (BP-53-12)	116	C4D (C4D204)	144	PAX-2 (EP235)
89	VIMENTIN (V9)	117	Prostatic Acid Phosphatase (EP53)	145	FSH (EP257)
90	P63 (4A4)	118	CD8 (C8/468)	146	Growth hormone (EP267)
91	CK5 & CK6 (EP24/EP67)	119	MUC1 (EP85)	147	Prolactin (EP193)
92	EMA (E29)	120	CD43 (DF-T1)	148	MUC2 (EP187)
93	CD19 (EP169)	121	CD44 (EP44)	149	NKX2.2 (NX2/294)
94	TdT (EP266)	122	ALK (1A4)	150	COX2 (SP21)
95	CD15 (BRA-4F1)	123	CD3 (Polyclonal)	151	PD1 (EP239)
96	MUM1 (EP190)	124	CD57 (NK1)	152	GATA-3 (L50-823)
97	CD68 (KP1)	125	TTF-1 (EP229)	153	KERATIN (CAM5.2)
98	HepPar1 (OCH1E5)	126	Glypican 3 (1G12+GPC3/863)	154	INI-1 (25)
99	DESMIN (GM007)	127	PSMA (EP192)	155	ACTH (AH26+57)
100	Cytokeratin 14 (LL002)	128	Myogenin (EP162)	156	CA19.9 (121SLE)
101	CD45RB (LCA) (2B11+PD7/26)	129	BCL-6 (EP278)	157	OCT-2 (EP115)
102	Inhibin alpha (R1)	130	Glycophorin-A (EP213)	158	PD1 (PDCD1/922)
103	Synaptophysin (EP158)	131	CD15 (EP273)	159	IDH1 (Isocitrate Dehydrogenase) (IDH1/1152 (Wild Type))
104	MELAN-A (MART-1) (A103)	132	LYSOZYME (EP134)	160	KI67 (MIB-1)
105	CD38 (EP135)	133	Myoglobin (EP87)	161	IgG4 (EP138)
106	Calretinin (Rabbit Polyclonal)	134	Cyclin E1 (EP126)	162	Uroplakin III (EP321)
107	SOX10 (EP268)	135	TLE1 (1F5)	163	TNF-alpha (TNF1172)
108	MUC4 (EP256)	136	COX2 (EP293)	164	AFP (Polyclonal)
109	Von Willebrand factor (Rabbit Polyclonal)	137	PGP9.5 (Polyclonal)	165	C4D (EP272)
110	Cytokeratin 19 (EP72)	138	PsAP (PASE/4LJ)	166	LH ALPHA (Lha/756)
111	Glut-1 (SLC2A1) (EP141)	139	Factor XIII A (EP292)	167	TSH (EP254)
112	Human Placental Lactogen (HPL) (EP241)	140	Cytokeratin 10 (EP97)	168	TFE3 (EP285)



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Sr. No.	Product Name	Sr. No.	Product Name	Sr. No.	Product Name
169	IMP-3 (EP286)	197	Myosin Heavy Chain (EP166)	225	CD205 (EP176)
170	Clusterin / Apolipoprotein J (EP181)	198	Galectin -3 (B2C10)	226	Granzyme B (EP230)
171	CD8 (EP334)	199	CPS1 (Hep Par-1) (EP265)	227	CD44 (HCAM/918)
172	ALK (EP302)	200	Myosin Light Chain (EP166)	228	olig2 (EP112)
173	NSE gamma (ENO2/1462)	201	KIM-1 (HAVcr-1) (EP309)	229	SOX11 (CLO142)
174	NKX3.1 (EP356)	202	RRM1 (EP242)	230	ANNEXIN A1 (BSB-95)
175	SALL4 (EP299)	203	MDR1 (EP271)	231	Ep CAM / CD326 (MOC31)
176	CD163 (EP324)	204	CD103 (EP206)	232	Fascin-1 (SPM133)
177	ATRX (D-5)	205	STAT-6 (EP325)	233	TRIM29 (TRIM29/1041)
178	ARGINASE 1 (ARG1/1125+ARG1/1126)	206	MDM2 (D7)	234	CD3 (PS1)
179	PODOPLANIN (D2-40)	207	ANNEXIN-VII (EP367)	235	Collagen Type IV (CO4P)
180	CDK4 (EP180)	208	CD209 (DC-SIGN) (C209/1781)	236	Cytokeratin 18 (EP30)
181	MUC5AC (CLH2)	209	Serum Amyloid A (EP335)	237	Myelin basic protein (EP207)
182	Parathyroid Hormone (PTH) (PTH/911)	210	CD95 (EP208)	238	SOX9 (EP317)
183	CD35 (EP197)	211	COL1A1 (EP236)	239	CD90 (EP56)
184	ALDH1A1 (EP168)	212	FOXP3 (EP340)	240	Perforin-1 (PRF1/2470)
185	Histone H3 Phospho(pT3) (EP233)	213	Geminin (EP355)	241	PD-L1 (B7H1P)
186	TRANSCRIPTION FACTOR PU.1 (EP18)	214	GATA3 (EP368)	242	p16 INK4A (JC8)
187	SATB2 (EP281)	215	MCM6 (EP375)	243	CD30 (TRA30P)
188	DOG 1 (EP332)	216	Langerin (CD207) (EP349)	244	Topoisomerase II α (TI2aP)
189	MCM5 (EP84)	217	PAX-8 (EP331)	245	hCG (CGP)
190	OCT2 (EP284)	218	HSP70 (EP377)	246	P40 (delta NPP)
191	FOXA1 (EP277)	219	ALPHA-1-ANTICHYMOTRYPSIN (EP384)	247	CD10 (MMEP)
192	FOXP1 (EP137)	220	CD248(Endosialin) (EP383)	248	NeuN (PFOX3)
193	CD41 (EP178)	221	MMP7 (EP388)	249	PD-L1 (CD274) (B7-H1) (RM320)
194	HLA-DRB1 (EP191)	222	GRIA2 (EP387)	250	SATB2 (PRM111)
195	Helicobacter Pylori (EP279)	223	Nucleophosmin (28M1)	251	MSH2 (PRM112)
196	ANTI-NeuN (A60)	224	Prostein-P501S,SLC45A3 (EP381)	252	KI-67 (PRM113)

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Sr. No.	Product Name	Sr. No.	Product Name	Sr. No.	Product Name
253	P63 (PRM114)	283	Cytokeratin 8 (IFGP)	313	HCG-BETA (CGBP)
254	P40 (PRM115)	284	Cytokeratin 8 & 18 (IFGFP)	314	Uroplakin III (P35P)
255	HER2 (c-erbB-2) (PRM116)	285	CD3 (TCRP)	315	Somatostatin (SRIP)
256	CD117/c-kit (PRM117)	286	PAX5 (BCMP)	316	CYCLIN-D1 (PRM132)
257	CD8a (PRM118)	287	AMACR (BOFAP)	317	CD15 (MMA)
258	MSH3 (PRM119)	288	ZAP70 (SYKP)	318	BRG-1 (SNFP)
259	ZAP70 (PRM120)	289	Galectin-3 (EP412)	319	PAX 8 (PRM133)
260	ANTI P16 INK4a (PRM121)	290	CD10 (NEPP)	320	PRAME (EP461)
261	Progesterone Receptor (PRM122)	291	EBV LMP-1 (3H2104 a, b, c)	321	OCT3/4 (OTFP)
262	PMS2 (MMRP)	292	BRAF (PRM130)	322	HER 2 (NGLP)
263	CD56 (PRM123)	293	hCG (PRM131)	323	Caldesmon (ZM79)
264	Napsin-A (PRM124)	294	ROS1 (EP282)	324	CD4 (TYP)
265	ANTI BRAF-V600E (RM8)	295	L1CAM (CD171) (EP411)	325	Mammaglobin (SGAP)
266	BOB1/OBF1 (PRM126)	296	Carbonic Anhydrase-9 (EP161)	326	Lambda Light Chain (MCGP)
267	TPO (THYROID PEROXIDASE) (PRM127)	297	LI -Cadherin (EP86)	327	MSH6 (GTBP)
268	MyoD1 (HLHTP)	298	WT1 (GUDP)	328	CD5 (LEU1P)
269	CD30 (PRM128)	299	PAX2 (FSGSP)	329	CD7 (LEU9P)
270	P53 (PRM129)	300	TdT (DNTP)	330	CD99 (MIC2P)
271	CD20 (BCAP)	301	Calcitonin (PCTP)	331	CA125 (M16P)
272	DOG1 (ANO1P)	302	CD138 (SDCP)	332	Annexin A1 (EP433)
273	E-CADHERIN (CDCAP)	303	Muscle Actin (HUC1-1)	333	GFAP (FLJP)
274	Ep CAM (TMGP)	304	Cytokeratin 5&6 (EBS1P)	334	CD79a (MB1P)
275	ERG (ETSP)	305	Cytokeratin PAN (EHKP)	335	CD35 (KNP)
276	SOX10 (SRYP)	306	Cytokeratin 17 (EP98)	336	SALL4 (ZPSP)
277	Synaptophysin (SYPP)	307	CD13 (EP117)	337	CALD1 (PRM134)
278	TTF-1 (HBPP)	308	HIF-1 Alpha (EP118)	338	p21 (CIP1P)
279	CDX2 (TSGP)	309	Top2a (PRM125)	339	TCL1 (EP105)
280	VILLIN (ACBP)	310	P53 (DO-7)	340	Cytokeratin (HMW) (K903P)
281	PMEL17 (GR100P)	311	KI-67 (PMPP)		
282	Myogenin (RPMDF)	312	ATRX (XH2P)		



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List of the products covered by the certificate

Annex 1 to Certificate No. - ECIC/IVDR/99-22

2. PolyExcel HRP/DAB Detection System: (One Step & Two Step)

3. Ancillaries for IHC Application:

- **Immunowash Buffers & Antigen Retrieval Buffers**
- **DAB Chromogen**
- **Microscopic Glass Slides**
- **Marking Pen (PAP Pen) & Diluents**
- **Staining Station**

Sr. No.	Product Name	Sr. No.	Product Name
1	PAP Pen	17	Tris-EDTA
2	Immunowash Buffer	18	Enhanced Citrate
3	Citrate Buffer	19	Modified Mayer's Hematoxylin
4	EDTA Buffer	20	Harris Hematoxylin
5	Tris-EDTA	21	Orange G6
6	Primary Antibody Diluents	22	EA50
7	Positively charged slides	23	Schiff's Reagent
8	Frosted Single Slides	24	Lillie's Hematoxylin
9	Frosted double slides	25	Enrich Primary Antibody Diluent
10	Cover Glass (100 pack)	26	Stunn DAB Kit
11	Microscopic Slides Plain (72 slides/Box)	27	10X PBS
12	Unispread (Poly lysine coated slides)	28	Eosin
13	3% Hydrogen Peroxide	29	Bluing Solution
14	Mayer's Hematoxylin	30	Detection Combo
15	Protein Block	31	Peroxidase Quencher
16	Enhanced Primary Antibody Diluent	32	Fast Freeze Cryogel



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4. Denaturation & Hybridization System

5. Special Stains:

Sr. No.	Product Name	Sr. No.	Product Name
1	PAP Stain (Modified Mayer's)	10	PAS Stain (Modified Mayer's)
2	Geimsa Stain	11	PAS Diastase Kit
3	Alcian Blue Stain	12	Warthin Starry Stain
4	Mucicarmine Stain	13	AFB Stain
5	Reticulin Stain	14	Oil-Red-O Stain
6	Congo Red Stain (Modified Mayer's)	15	Perl's Prussion Stain
7	PAP Stain (Harris Hematoxylin)	16	Verhoeff - Vangieson Stain
8	PAS Alcian Blue Stain	17	Jones Methanamine Silver (JMS) Stain
9	GMS Stain	18	Vonkossa Stain

6. HISTOPATHOLOGICAL INSTRUMENTS:

Sr. No.	Product Name
1	Microtome (PS-2260)
2	Embedding Centre with cooling plate (PS-TECL)
3	Advanced Embedding Centre with cooling plate (PS-ADECL)
4	Embedding Centre without cooling plate (PS-TEC)
5	Advanced Embedding Centre without cooling plate (PS-ADEM-IV)
6	Cooling Plate (PS-COL)
7	Tissue Processor (PS-TP3A)
8	Advanced Tissue Processor (PS-TP3S1)
9	Tissue Flootation Bath/Water Bath (PS-WB)
10	Slide Warming Table/Slide Dryer (PS-SD)
11	Grossing Station with Profile (PSGS-4P, PSGS-5P, PSGS-6P)
12	Grossing Station Without Profile (PSGS-4, PSGS-5, PSGS-6)

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