



הרשות הלאומית להסמכת מעבדות
Israel Laboratory Accreditation Authority

Department: Testing Laboratory-Medical ISO 15189:2012 Accreditation No. 0197

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The certificate attached is an integral part of the schedule and is numbered identically התעודת המצורפת לנספח זה מהווה חלק בלתי נפרד ממנו ומספרה זהה למספר הנספח



Schedule of Accreditation

Item	Scope Type	Site	Types of Test / Properties Measured	Materials / Samples Tested	Test principle / Characteristics	Equipment used / Work station	Opinion and Interpretation	Remarks	
Group of products: Health, Medicine - Pathology			משפחת מוצרים: בריאות, רפואה - פתולוגיה						
Chemical, Biological Testing, Classical Stains, Cytopathology			בדיקות כימיות, ביולוגיות, צביעות קלאסיות, ציטופתולוגיה						
1	C	P	FNA stain For non-gyn cytology	FNA צביעת לציטולוגיה כללית	Cell suspension/ Cytological slides	תרחיף תאים/ סלייד ציטולוגי	Microscopy	centrifuge, Slide stainer, cover slipper, Bright Field Microscope ---	FNA=Fine Needle Aspiration For Type C details see list no. PAT-01-FG-100-E
2	C	P	H&E stain For urine cytology	H&E צביעת לציטולוגית שתן	Cell suspension	תרחיף תאים	Microscopy	centrifuge/cytospin Slide stainer, ThinPrep5000, cover slipper, Bright Field Microscope ---	For Type C details see list no. PAT-01-FG-100-E
3	C	P	LBC PAP preparation, imaging & screening	הכנה וסקירה של משטחי פאפ דק עם imaging	Cell suspension	תרחיף תאים	Microscopy	ThinPrep5000, slide stainer & cover slipper, Imaging system, review microscope, Bright Field Microscope ---	LBC = Liquid Based Cytology. ThinPrep/Hologic + Imaging system For Type C details see list no. PAT-01-FG-100-E

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Type of Scopes: A- Fixed, C- Flexible scope in analytical tests : Type of matrix, analytes, experimental systems and/or analytical characteristics may be subject to changes, in accordance with the laboratory's approved and documented procedures. For details, please refer to the list of Accredited Tests, available from the laboratory upon request.



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Group of products: Health, Medicine - Pathology				משפחת מוצרים: בריאות, רפואה - פתולוגיה						
Biological Testing, Molecular Methods, Cytopathology				בדיקות ביולוגיות, שיטות מולקולריות, ציטופתולוגיה						
4	C	P	HPV	בדיקת HPV	ThinPrep preserve medium	מדיום משמר של ThinPrep	PCR	Cobas HPV, Roche	---	For Type C details see list no. PAT-01-FG-100-E

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Group of products: Health, Medicine - Pathology				משפחת מוצרים: בריאות, רפואה - פתולוגיה						
Chemical, Biological Testing, Classical Stains, Histopathology				בדיקות כימיות, ביולוגיות, צביעות קלאסיות, היסטופתולוגיה						
5	C	P	Histotechnology – H&E stain	צביעות היסטוכימיות H&E	Histological slides	סלייד היסטולוגי	Microscopy	Slide stainer, cover slipper, Bright Field Microscope	---	H&E = Hematoxylin & Eosin For Type C details see list no. PAT-01-FG-100-E
6	C	P	Histotechnology – Special Stains	צביעות היסטוכימיות מיוחדות	Histological slides	סלייד היסטולוגי	Microscopy	Nexes for Special Stains Slide stainer, cover slipper, Bright Field Microsc	---	For Type C details see list no: 011_A_3 For Type C details see list no. PAT-01-FG-100-E
7	C	P	Preparation of FFPE blocks	הכנת בלוק פרפין	Tissue in formalin, Cell suspension	רקמות בפורמלין תרחיף תאים	Intermediate product	Cassette printer, Tissue processor, embedding center	---	FFPE= Formalin Fixed Paraffin Embedded For Type C details see list no. PAT-01-FG-100-E
8	C	P	Preparation of unstained slides	הכנת חתכים היסטולוגיים לא צבועים	FFPE blocks, Cell blocks	בלוק פרפין Cell blocks	Intermediate product	Microtome, cold plate, floating bath, label printer	---	For Type C details see list no. PAT-01-FG-100-E

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Group of products: Health, Medicine - Pathology				משפחת מוצרים: בריאות, רפואה - פתולוגיה					
Chemical, Biological Testing, Classical Stains, Histopathology, Immunohistochemistry				בדיקות כימיות, ביולוגיות, צביעות קלאסיות, היסטופתולוגיה, אימונוהיסטוכימיה					
9	C	P	IHC – specific Abs for protein detection	צביעות אימונוהיסטוכימיות לזיהוי חלבונים	Histological slides	סלייד היסטולוגי	Microscopy	IHC Autostainer (ULTRA), cover slipper, Bright Field Microscope	IHC= Immuno Histo Chemistry For Type C details see list no. PAT-01-FG-100-E

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Schedule of Accreditation

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Biological Testing, Molecular Methods, Histopathology				בדיקות ביולוגיות, שיטות מולקולריות, היסטופתולוגיה					
10	C	P	FISH For the detection of genomic aberrations	FISH לגילוי אברציות כרומוזומליות	Histological slides	סלייד היסטולוגי	Microscopy	Fluorescent Microscope	FISH= Fluorescent In Situ Hybridization 1) Her2/neu- Vysis Pathvision kit 2) Vysis ALK Break Apart FISH Probe Kit 3) Vysis MDM2/CEP 12 4) Vysis Bcl-2 break apart FISH probe kit 5) Vysis Bcl-6 break apart FISH probe kit 6) Vysis c-Myc break apart FISH probe kit 7) ZytoLight® SPEC ROS1 Dual Color Break Apart Probe For Type C details see list no. PAT-01-FG-100-E
11	C	P	PCR For B- and T-cell rearrangement (monoclonality)	בדיקות PCR לקלונליות של תאי B ו-T.	DNA extracted from FFPE blocks	דנ"א שהופק מבלוק פרפין	Heteroduplex analysis	PCR, electrophoresis UV camera	PCR= Polymerase Chain Reaction In house method- primers according to BIOMED-2 For Type C details see list no. PAT-01-FG-100-E
12	C	P	PCR for MSI	בדיקת PCR לגילוי חוסר יציבות גנטית	DNA extracted from FFPE blocks	דנ"א שהופק מבלוק פרפין	PCR	GeneScan	MSI=Microsatellite Instability Promega kit For Type C details see list no. PAT-01-FG-100-E

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