March 2019

ALLINA HEALTH LABORATORY

LabConnect

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INSM1

Effective immediately, the Allina Health Immunohistochemistry laboratory is performing the INSM1 stain.

Applications:

- INSM1 is positive in neuroendocrine tumors and in normal adult neuroendocrine tissues and developing neurons.
- INSM1 positivity has been described in the following neoplasms:
  - ◊ CNS tumors: Pituitary adenoma, central neurocytoma, medulloblastoma, glioblastoma, pineal parenchymal tumor
  - ◊ Endocrine: Adrenal pheochromocytoma, paraganglioma, medullary carcinoma of the thyroid, and neuroblastoma
  - ◊ Gastrointestinal tract: Pancreatic neuroendocrine tumors (100%) and gastrointestinal neuroendocrine tumors (100%)
  - ◊ Lung: Small cell carcinoma (95%), large cell neuroendocrine carcinoma (90%), typical and atypical carcinoid (100%). Weak or focal positivity has been reported in lung adenocarcinomas (3%) and squamous cell carcinomas (4%).
  - ◊ Skin: Merkel cell carcinoma (93%), endocrine mucin producing sweat gland carcinoma
  - ◊ Soft tissue tumors: Extraskeletal myxoid chondrosarcoma (90%), chordoma (10%), soft tissue myoepithelioma (5%), ossifying fibromyxoid tumor (30%), and Ewings sarcoma (30%)
- INSM1 positivity has been reported in the following in tumors with neuroendocrine differentiation: Breast adenocarcinoma, colonic adenocarcinoma, endometrioid carcinoma, and prostate adenocarcinoma

Test Name:	INMS1 by IHC
Test Number:	12376 - Technical only; 12379 - Technical & Interpretation
Collect:	Formalin-fixed, paraffin embedded (FFPE) tissue block. *All IHC stains will include a positive control tissue on each slide.*
Container:	FFPE tissue block
Processing:	Submit processed tissue block
Transport/Stability:	Ambient (preferred)
Alternate Names:	IHC
Performing Lab:	AHL – Immunohistochemistry
Days Set Up:	Mo – Fr
Expected TAT:	1 - 2 days
Ref. Ranges:	If requested, an interpretive report will be provided

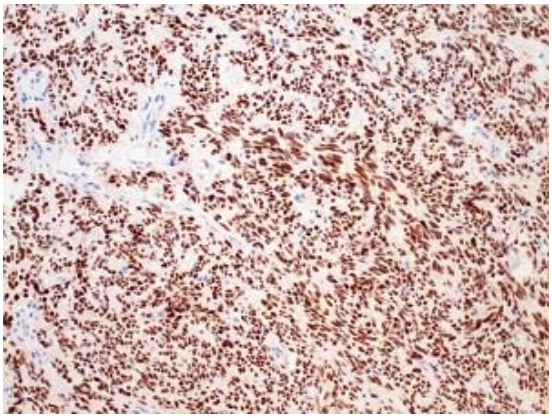
Test Name: INMS1 by IHC
Test Number: 12376 - Technical only
12379 - Technical & Interpretation
Collect: Formalin-fixed, paraffin embedded (FFPE) tissue block.
All IHC stains will include a positive control tissue on each slide.
Container: FFPE tissue block
Processing: Submit processed tissue block
Transport/Stability: Ambient (preferred)
Alternate Names: IHC
LAB12376
LAB12379
Performing Lab: AHL – Immunohistochemistry
Days Set Up: Mo – Fr
Expected TAT: 1 - 2 days
Ref. Ranges: If requested, an interpretive report will be provided
Collection/ Processing Details:

Specifications:

Zinc finger transcription factor involved in development of normal neuro endocrine cells throughout the body and involved in tumor neuroendocrine differentiation.

Staining pattern:

Nuclear



Method: Immunohistochemical staining
Microscopic examination
CPT Codes: 88342 - 1st stain
88341 - each additional stain

References:

1. Ames HM et al. INSM1 expression is frequent in primary central nervous system neoplasms but not in the adult brain parenchyma. J Neuropathol Exp Neurol 2018;77(5):374-382.

2. Fujino K et al. INSM1 is the best marker for the diagnosis of neuroendocrine tumors: comparison with CGA, SYP and CD56. Int J Clin Exp Pathol 2017;10(5):5393-5405.

3. Lilo MT et al. INSM1 is more sensitive and interpretable than conventional immunohistochemical stains used to diagnose merkel cell carcinoma. Am J Surg Pathol 2018;42(11):1541-1548.

4. Rosenbaum JN et al. A novel immunohistochemical and molecular marker for neuroendocrine and neuroepithelial neoplasms. Am J Clin Pathol 2015;144:579-591.

5. Rooper LM et al. INSM1 demonstrates superior performance to individual and combined use of synaptophysin, chromogranin and CD56 for diagnosing neuroendocrine tumors of the thoracic cavity. Am J Surg Pathol 2017;41(11):1561-1569.

6. Yoshinda et al. INSM1 expression and its diagnostic significance in extraskeletal myxoid chondrosarcoma. Mod Pathol 2018;31:744-752.

T-pit (clone CL6251)

Effective immediately, the Allina Health Immunohistochemistry Laboratory is performing the T-Pit (clone CL6251) stain.

T-Pit is used in conjunction with SF-1 and Pit-1 immunohistochemical stains to classify pituitary adenomas. The presence of T-Pit nuclear reactivity within a monomorphous population of neuroendocrine cells within the sella turcica strongly supports adrenocorticotropin lineage. T-Pit is considered to be more sensitive and specific than ACTH IHC [6].

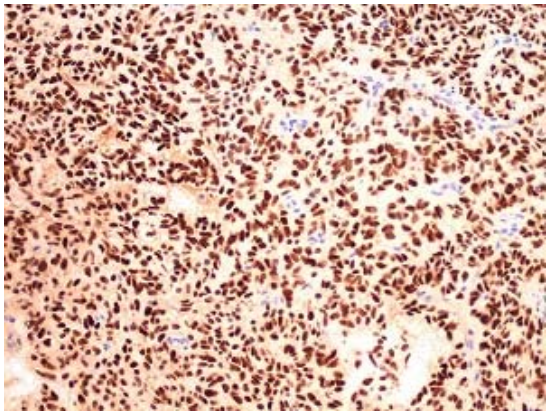
Test Name:	T-Pit (clone CL6251) by IHC
Test Number:	12376 - Technical only 12379 - Technical & Interpretation
Collect:	Formalin-fixed, paraffin embedded (FFPE) tissue block. *All IHC stains will include a positive control tissue on each slide.*
Container:	FFPE tissue block
Processing:	Submit processed tissue block
Transport/Stability:	Ambient (preferred)
Alternate Names:	IHC, LAB12376, LAB12379
Performing Lab:	AHL – Immunohistochemistry
Days Set Up:	Mo – Fr
Expected TAT:	1 - 2 days
Ref. Ranges:	If requested, an interpretive report will be provided

Specifications:

T-Pit (T-box family member TBX19) regulates the proopiomelanocortin (POMC) lineage giving origin to corticotrophs

Staining pattern:

- Nuclear staining
- Normal adenohypophysis shows T-Pit positivity in scattered cells and cell clusters
- Positive in pituitary adenomas of adrenocorticotropin lineage



Applications:

T-Pit is used in conjunction with SF-1 and Pit-1 immunohistochemical stains to classify pituitary adenomas. The presence of T-Pit nuclear reactivity within a monomorphous population of neuroendocrine cells within the sella turcica strongly supports adrenocorticotropin lineage. T-Pit is considered to be more sensitive and specific than ACTH IHC [6].

Method:

Immunohistochemical staining and microscopic examination

CPT Codes:

88342 - 1st stain, 88341 - each additional stain

References:

1. Asa SL. Practical pituitary pathology: what does the pathologist need to know? Arch Pathol Lab Med. 2008;132(8):1231-40.
2. Asa S. Tumors of the Pituitary Gland. Silverberg SG, editor. Washington, DC: American Registry of Pathology; 2011. 283 p.
3. Mete O, Cintosun A, Pressman I, Asa SL. Epidemiology and biomarker profile of pituitary adenohypophysial tumors. Mod Pathol. 2018;12(10):018-0016.
4. Lamolet B, Pulichino AM, Lamonerie T, Gauthier Y, Brue T, Enjalbert A, et al. A pituitary cell-restricted T box factor, Tpit, activates POMC transcription in cooperation with Pitx homeoproteins. Cell. 2001;104(6):849-59.
5. Pulichino AM, Vallette-Kasic S, Couture C, Gauthier Y, Brue T, David M, et al. Human and mouse TPIT gene mutations cause early onset pituitary ACTH deficiency. Genes Dev. 2003;17(6):711-6.
6. Sjostedt E, Bollerslev J, Mulder J, Lindskog C, Ponten F, Casar-Borota O. A specific antibody to detect transcription factor T-Pit: a reliable marker of corticotroph cell differentiation and a tool to improve the classification of pituitary neuroendocrine tumours. Acta Neuropathol. 2017;134(4):675-7. doi: 10.1007/s00401-017-1768-9. Epub 2017 Aug 19.
7. McDonald WC, Banerji N, McDonald KN, Ho B, Macias V, Kajdacsy-Balla A. Steroidogenic Factor 1, Pit-1, and Adrenocorticotropic Hormone: A Rational Starting Place for the Immunohistochemical Characterization of Pituitary Adenoma. Arch Pathol Lab Med. 2017;141(1):104-12.

REFERRAL TESTING

Test formulary update

Allina Health has a system-wide Laboratory Stewardship program, and as a part of that program, conducts ongoing review of test utilization. For quality and compliance reasons, ***effective April 1, 2019,*** the laboratory tests shown in the table on the following page, ordered as a Miscellaneous Sendout (MSO, 994/LAB994), will be excluded from the Allina Health Test Formulary.

The listed tests will no longer be collected, orderable, or available through Allina Health and any future orders received will be cancelled. Allina Health Laboratory provides an extensive formulary of referral laboratory tests that meet established criteria for appropriateness, medical necessity, quality, compliance, patient safety, and clinical validity.

If you have any questions about this formulary change, please contact your Allina Health Laboratory account representative.

Tests to be removed from formulary April 1, 2019	Reason for removal from formulary
Histamine, Whole blood	**Tests performed for research purposes only** These tests are not validated for clinical use. Per Allina Health's Laboratory policy and accreditation standards, research tests are excluded from our test formulary.
Matrix metalloproteinase-9 (MMP-9)	
Vascular Endothelial Growth Factor (VEGF)	
HNK1 (CD57) Panel	
Transforming Growth Factor beta (TGF-b)	
Glutathione	
Leptin	
C4ades Arg Level	
Pyrroles, urine	**Tests sent to a non-approved referral laboratory** Allina Health referral laboratory policy requires that all patient testing be performed by laboratories with both CLIA and CAP certification. Although some tests are orderable from one of our approved referral labs, they are subsequently referred on to non-CAP-accredited laboratories.
Alpha Melanocyte-stimulating Hormone	
Lipid Peroxides	

If providers at your site wish to continue to utilize any of these tests, the samples must be transported from your site directly to the testing/performing laboratory.

Angiotensin converting enzyme (ACE)

Mayo Clinic Laboratories (MCL) has announced updates to the reference value, requested volume and specimen stability for the Angiotensin converting enzyme assay (14/82164.1). On April 10, 2019, the following changes to the Angiotensin converting enzyme will go into effect.

Current Reference Value
> or =18 years: 8-53 U/L The reference interval for pediatric patients may be up to 50% higher than that of adults.

New Reference Value
> or =18 years: 16-85 U/L 0Y-17Y: ACE activity may be 20-50% higher in healthy children compared to healthy adults (16-85 U/L)

Current Requested Volume
1.0 mL

New Requested Volume
0.5 mL

Current Specimen Stability		
Specimen	**Temperature**	**Time**
Serum	Refrigerated (preferred)	7 days
	Frozen	180 days

New Specimen Stability		
Specimen	**Temperature**	**Time**
Serum	Refrigerated (preferred)	7 days
	Frozen	180 days
	Ambient	24 hours

Chloride, body fluid

Mayo Clinic Laboratories (MCL) has announced that due to low utilization, effective March 26, their Chloride, body fluid assay (51/82438.0, MCL# CLBF) will become obsolete. The suggested alternative test is the Chloride, body fluid (994/LAB994) referred to LabCorp. Test ordering and specimen information for this test are as detailed below.

Test Name:	Chloride, body fluid
Test Number:	994
Collect:	1.0 mL (minimum 0.3 mL) body fluid
Container:	Sterile container
Processing:	State source
Transport/Stability:	Refrigerated
Alternate names:	Cl, MSO, LAB994
Performing Lab:	LabCorp Burlington (100461); R-NX
Days Set Up:	Daily
Expected TAT:	1 - 3 days
Ref. Ranges:	Not established
Method:	Ion-selective electrode
CPT code	82438

Potassium, body fluid

Mayo Clinic Laboratories (MCL) has announced that due to low utilization, effective March 26, their Potassium, body fluid assay (50/84133.1, MCL# KBF) will become obsolete. The suggested alternative test is the Potassium (fluid) (994/LAB994) assay, referred to LabCorp. Test ordering and specimen information for this test are as detailed below.

Test Name:	Potassium (fluid)
Test Number:	994
Collect:	1.0 mL (minimum 0.3 mL) body fluid
Container:	Sterile container
Transport/Stability:	Refrigerated
Alternate Names:	K+, MSO, LAB994
Performing Lab:	LabCorp Burlington (100230); R-NX
Days Set Up:	Daily
Expected TAT:	1 - 3 days
Ref. Ranges:	Not established
Collection/ Processing Details:	Include source
Method:	Ion-selective electrode
CPT Codes:	84999

Sodium, body fluid

Mayo Clinic Laboratories (MCL) has announced that due to low utilization, effective March 26, their Sodium, body fluid assay (49/82438.1, MCL# NABF) will become obsolete. The suggested alternative test is the Sodium (fluid) (994/LAB994) assay, referred to LabCorp. Test ordering and specimen information for this test are as detailed below.

Test Name:	Sodium (fluid)
Test Number:	994
Collect:	1.0 mL (minimum 0.3 mL) body fluid
Container:	Sterile container
Transport/Stability:	Refrigerated
Alternate Names:	Na, MSO, LAB994
Performing Lab:	LabCorp Burlington (100248); R-NX
Days Set Up:	Daily
Expected TAT:	1 - 3 days
Ref. Ranges:	Not established
Collection/Processing Details:	State source
Method:	Ion-selective electrode
CPT Codes:	84302