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Medical Laboratory Sorrento Mesa

Abbott Alinity Immunoassay Reference range

Effective 3/28/2022

Assay	Reference Range	Comments to auto-append
AFP	2.0 - 8.78 ng/mL	This result was obtained using Abbott Alinity Chemiluminescent microparticle immunoassay (CMIA). Values obtained with different assay methods cannot be used interchangeably.
Anti-CCP	<5.0 U/mL	Alinity i Anti-CCP results should not be used interchangeably with other manufacturers' methods for anti-CCP determinations.
Anti-TPO	<5.61 IU/mL	
B-hCG	0 - 5 mIU/mL	The Alinity i Total β-hCG assay is cleared for use in the early detection of pregnancy only. It is not approved for any other uses such as tumor marker screening, tumor marker monitoring, etc. and it should not be performed for any other uses.
CA 125 II	0 - 35 U/mL	This result was obtained using Abbott Alinity Chemiluminescent microparticle immunoassay (CMIA). Values obtained with different assay methods cannot be used interchangeably.
CA 19-9XR	0 - 37 U/mL	This result was obtained using Abbott Alinity Chemiluminescent microparticle immunoassay (CMIA). Values obtained with different assay methods cannot be used interchangeably.
CEA	0 - 5 ng/mL	This result was obtained using Abbott Alinity Chemiluminescent microparticle immunoassay (CMIA). Values obtained with different assay methods cannot be used interchangeably.
CK-MB	Male: 0 - 7.2 ng/mL Female: 0 - 3.4 ng/mL	
C-Peptide	0.78 - 5.19 ng/mL	
Cortisol, Random	2.9 - 19.4 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone (which is converted to prednisolone in vivo) may show artificially elevated cortisol values due to cross-reactivity.

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Assay	Reference Range	Comments to auto-append
Cortisol AM	3.7 - 19.4 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone (which is converted to prednisolone in vivo) may show artificially elevated cortisol values due to cross-reactivity.
Cortisol PM	2.9 - 17.3 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone (which is converted to prednisolone in vivo) may show artificially elevated cortisol values due to cross-reactivity.
Cortisol Baseline	2.9 - 19.4 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone may show artificially elevated cortisol values due to cross-reactivity.
Cortisol 30 min post cortrosyn	>14.0 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone may show artificially elevated cortisol values due to cross-reactivity.
Cortisol 45 min post cortrosyn	>14.0 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone may show artificially elevated cortisol values due to cross-reactivity.
Cortisol 60 min post cortrosyn	>14.0 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone may show artificially elevated cortisol values due to cross-reactivity.
Cortisol Post Dexamethasone	<5.0 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone may show artificially elevated cortisol values due to cross-reactivity.
Cortisol Post Stimulation	>14.0 mcg/dL	Patients receiving fludrocortisone, prednisolone or prednisone may show artificially elevated cortisol values due to cross-reactivity.

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DHEA-S	**FEMALES:** Age in years: Range: mcg/dL 0-11 Not established 11-15 8.6-169.8 15-20 61.2-493.6 20-25 134.2-407.4 25-35 95.8-511.7 35-45 74.8-410.2 45-55 56.2-282.9 55-65 29.7-182.2 65-70 33.6-78.9 70 and older Not established **MALES:** Age: Range: mcg/dL 0-11 Not established 11-15 16.6-242.7 15-20 45.1-385.0 20-25 238.4-539.3 25-35 167.9-591.9 35-45 139.7-484.4 45-55 136.2-447.6 55-65 48.6-361.8 65-70 228.5-283.6 70 and older Not established	
Estradiol	Category/ Phase: Range: pg/mL Normal menstruating Females: Follicular 21-251 Midcycle 38-649 Luteal 21-312 Post-menopausal Females: Not on HRT <10-28 On HRT <10-144 Males: 24-44	

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Assay	Reference Range	Comments to auto-append
Ferritin	Males: 21.81 – 274.66 ng/mL Females: 4.63 – 204.00 ng/mL	
Folate	7.0 - 31.4 ng/mL	
Free T3	1.58 - 3.91 pg/mL	
Free T4	0.70 - 1.48 ng/dL	
FSH	Category/ Phase: Range: mIU/mL Normal menstruating Females: Follicular 3.03-8.08 Midcycle 2.55-16.69 Luteal 1.38-5.47 Post-menopausal Females: 26.72-133.41 Males: 0.95-11.95	
HCY	Male: 5.46 - 16.20 mcmol/L Female:4.44 - 13.56 mcmol/L	The following drugs may elevate levels of homocysteine: methotrexate, carbamazepine, phenytoin, nitrous oxide, anticonvulsants and 6-azauridine triacetate. S-adenosyl-methionine is an antidepressant may interfere with the Alinity i Homocysteine assay.
Insulin	2 – 28.0 mcgU/mL	
iPTH	8.5 - 72.5 pg/mL	

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Assay	Reference Range	Comments to auto-append
LH	Category/ Phase: Range: mIU/mL Normal menstruating Females: Follicular 1.80-11.78 Midcycle 7.59-89.08 Luteal 0.56-14.0 Post-menopausal Females: Without HRT 5.16-61.99 Males: 0.57-12.07	
Progesterone	Category/ Phase: Range: ng/mL Normal menstruating Females: Follicular <0.1-0.3 Luteal 1.2-15.9 Post-menopausal Females: <0.1-0.2 Pregnant Females: First trimester 2.8-147.3 Second trimester 22.5-95.3 Third trimester 27.9-242.5 Males: <0.1-0.2	
Prolactin	Males: 3.46 - 19.40 ng/mL Females: 5.18 – 26.53 ng/mL	
SHBG	Male: 11.2 - 78.1 nmol/L Female: 11.7 - 137.2 nmol/L	
Sirolimus	See comment	Patient assessment required. Therapeutic range dependent upon the type of transplant, time the dose was administered, and other drugs administered to the patient. Methodology: Chemiluminescent microparticle immunoassay (CMIA). Platform: Abbott Alinity

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Assay	Reference Range	Comments to auto-append
Tacrolimus	See comment	Patient assessment required. Therapeutic range dependent upon the type of transplant, time the dose was administered, and other drugs administered to the patient. Methodology: Chemiluminescent microparticle immunoassay (CMIA). Platform: Abbott Alinity
Testosterone	Males (21-49 yrs): 240.24 – 870.66 Males (≥50 yrs): 220.91 – 715.81 Females (21-49 yrs): 13.84 – 53.35 Females (≥50 yrs): 12.40 – 35.76	A strong interaction with D-(-) Norgestrel (1000 ng/mL), 19-nortestosterone (Nandrolone), Ethisterone, 11b-Hydroxytestosterone, and 11-Ketotestosterone was found. Do not use samples from patients receiving these compounds.
Total PSA	< 4.0 ng/mL	This result was obtained using Abbott Alinity Chemiluminescent microparticle immunoassay (CMIA). Values obtained with different assay methods cannot be used interchangeably. The Abbott Alinity i Total PSA assay was used. The Abbott assay is approved as an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older, or as an adjunctive test to aid in the management of prostate cancer patients. Elevated PSA concentrations can only suggest the presence of prostate cancer. Prostatic biopsy is required for diagnosis of cancer. Elevated concentrations of PSA may be observed in the serum of patients with benign prostatic hyperplasia or other nonmalignant disorders. Low PSA concentrations are not always indicative of the absence of cancer. Hormonal therapy may affect PSA expression.
Total T3	0.35 - 1.93 ng/mL	

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Assay	Reference Range	Comments to auto-append
Total T4	4.87 - 11.72 mcg/mL Critical values 0-28 days old: <5.0 mcg/dL >20.0 mcg/dL	
TSH	0.35 to 4.94 mcIU/mL Critical values 0-28 days old: <0.1 mcIU/mL >10.0 mcIU/mL	
Vitamin B12	213 - 816 pg/mL	
Vit D25OH	0-18 years: 20-80 ng/mL 18 years and older: 30-90 ng/mL	0-18 years old: Deficiency < 20 ng/mL Optimal level ≥ 20 ng/mL Potential toxicity > 100ng/mL Wagner CL et al. Pediatrics 2008; 122: 1142-52 18 years and older: Deficiency < 20 ng/mL Insufficiency 20-29 ng/mL Optimal level ≥ 30 ng/mL Potential toxicity > 100ng/mL Patients whose predominant form of vitamin D is D2, such as those receiving vitamin D2 supplementation, results that are subtherapeutic should be confirmed with another method, such as LC-MS/MS.

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INFECTIOUS DISEASE:

Assay	Reference Range	Comments to auto-append	Resulting S/CO – Interpretation
Hep A IgG	Non-Reactive		< 1.0 **Non-Reactive** ≥ 1.0 **Reactive**
Hep A IgM	Non-Reactive	Non-Reactive: A negative test result does not exclude the possibility of exposure to hepatitis A virus. Levels of IgM anti-HAV may be below the cutoff in early infection and late acute infection. Equivocal: Patients exhibiting equivocal results should be closely monitored by redrawing and retesting at approximately one-week intervals. Reactive: The positive anti-HAV IgM test is consistent with recent or current Hepatitis A infection. A reactive IgM anti-HAV result does not necessarily rule out other hepatitis infections. Reactive: SDPH comment: These results have been reported to the San Diego Department of Health Services as required by Title 17, California Code of regulations, Section 2505.	< 0.80 **Non-Reactive** 0.80 – 1.20 **Equivocal** ≥ 1.21 **Reactive**

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Assay	Reference Range	Comments to auto-append	Resulting S/CO – Interpretation
Hep B core Total	Non-Reactive	A nonreactive test result does not exclude the possibility of exposure to or infection with HBV.	< 0.80 **Non-Reactive** 0.80 – 1.20 **Equivocal** **Retest sample in duplicate** 2 of 3 Result: <0.80 Non-Reactive 0.80-1.20 Equivocal ≥ 1.21 Reactive ≥ 1.21 **Reactive** **Retest sample in duplicate** 2 of 3 Result: <0.80 Non-Reactive 0.80-1.20 Equivocal ≥ 1.21 Reactive **(Reflexes to Hep B core IGM)**
Hep B core IgM	Non-Reactive	Non-Reactive: A nonreactive test result does not exclude the possibility of exposure to or infection with HBV. Equivocal: Patients exhibiting equivocal results should be closely monitored by redrawing and retesting at approximately one-week intervals. Positive: SDPH comment: These results have been reported to the San Diego Department of Health Services as required by Title 17, California Code of regulations, Section 2505.	< 0.80 **Non-Reactive** 0.80 – 1.20 **Equivocal** ≥ 1.21 **Reactive**

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Assay	Reference Range	Comments to auto-append	Resulting S/CO – Interpretation
Hep C Ab	Non-Reactive	Non-Reactive: A nonreactive test result does notexclude the possibility of exposure to or infection with HCV. Immunocompromised patients who have HCV may produce levels of antibody below the sensitivity of this assay and may not be detected as positive. Equivocal for Hep C Ab: Supplemental testing is recommended for Equivocal result. Options include: retest in 2-4 weeks or PCR Hepatitis C testing (requires new sample). Equivocal for Hep C Ab with reflex to RNA quant PCR: For Equivocal result, supplemental testing is recommended. A reflex PCR test is being performed.For Reactive for Hep C Ab: A reactive result may indicate current HCV infection, past resolved HCV infection, or a false positive result. HCV RNA testing is recommended. Reactive for Hep C Ab with reflex to RNA quant PCR: A reactive result may indicate current HCV infection, past resolved HCV infection, or a false positive result. A reflex PCR test is being performed. See separate report.	0.0 – 0.79 **Non-Reactive** 0.80 – 0.99 **Equivocal** **Retest sample in duplicate** 2 of 3 Result: 0.0 – 0.79 Non-Reactive 0.80 – 0.99 Equivocal ≥ 1.0 Reactive ≥ 1.0 **Reactive**

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Assay	Reference Range	Comments to auto-append	Resulting S/CO – Interpretation
		Positive: SDPH comment: These results have been reported to the San Diego Department of Health Services as required by Title 17, California Code of regulations, Section 2505.	
Hep B surface Ab		Equivocal: The immune status of the individual should be further assessed by considering other factors, such as clinical status, follow-up testing, associated risk factors, and the use of additional diagnostic information.	**< 8.0 Non-Immune to HBV** **≥ 8.0 – 11.99 Equivocal** **Retest sample in duplicate** 2 of 3 Result: < 8.0 Non-Immune to HBV ≥ 8.0 – 11.99 Equivocal ≥ 12.0 Immune to HBV **≥ 12.0 Immune to HBV**
Hepatitis B surface Ag	Non-Reactive		**< 1.0 Non-Reactive** **≥ 1.0 Reactive** **Retest sample in duplicate** 2 of 3 Result: < 1.0 Non-Reactive ≥ 1.0 Reactive **(Reflexes to Hep B surface Ag Confirmatory)**
Hepatitis B surface Ag, Confirmatory	Negative	Positive: SDPH comment: These results have been reported to the San Diego Department of Health Services as required by Title 17, California Code of regulations, Section 2505.	* See table below

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<table>
<tr><th>Assay</th><th>Reference Range</th><th>Comments to auto-append</th><th>Resulting S/CO – Interpretation</th></tr>
<tr><td></td><td colspan="3">
* Hep B surface Ag Confirmatory Resulting Table
<table>
<tr><th>DILUTION</th><th>HBsAgQuC2 S/CO</th><th>% Neutralization</th><th>FINAL INTERPRETATION</th></tr>
<tr><td>NEAT (UNDILUTED)</td><td>< 0.70</td><td>Not applicable</td><td>Not confirmed/Negative</td></tr>
<tr><td></td><td>< 10.0</td><td>< 50 %</td><td>Not confirmed/Negative</td></tr>
<tr><td></td><td>≥ 0.70</td><td>≥ 50 %</td><td>Confirmed Positive</td></tr>
<tr><td></td><td>≥ 10.0</td><td>< 50 %</td><td>Repeat test using a 1:500 dilution</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>1:500</td><td>< 0.70</td><td>Not applicable</td><td>Not confirmed/Negative</td></tr>
<tr><td></td><td>≥ 0.70</td><td>≥ 50 %</td><td>Confirmed Positive</td></tr>
<tr><td></td><td>≥ 0.70</td><td>< 50 %</td><td>Repeat test using a 1:20 000 dilution</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>1:20 000</td><td>< 0.70</td><td>Not applicable</td><td>Not confirmed/Negative</td></tr>
<tr><td></td><td>≥ 0.70</td><td>≥ 50 %</td><td>Confirmed Positive</td></tr>
<tr><td></td><td>≥ 0.70</td><td>< 50 %</td><td>Not confirmed/Negative</td></tr>
</table>
</td></tr>
<tr><td>HIV Ag/Ab Combo</td><td>Non-Reactive</td><td>Reactive:
SDPH comment:
These results have been reported to the San Diego Department of Health Services as required by Title 17, California Code of regulations, Section 2505.</td><td>< 1.0 Non-Reactive

≥ 1.0 Reactive
Retest sample in duplicate
2 of 3 Result:
< 1.0 Non-Reactive
≥ 1.0 Reactive

(Reflexes to HIVMS)</td></tr>
<tr><td>Syphilis</td><td>Non-Reactive</td><td></td><td>< 1.0 Non-Reactive

≥ 1.0 Reactive</td></tr>
</table>

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PEDIATRIC REFERENCE RANGES (CALIPER)

AFP (ng/mL)

AGE	FEMALE/ MALE
0 - 1 month	>2000
1 - 6 months	10 - 1359
6 months – 1 year	0 - 103
1 - 19 years	2 - 35

FERRITIN (ng/mL)

AGE	FEMALE	AGE	MALE
0 – 14 days	99.6 – 717	0 – 14 days	99.6 – 717
15 days – 6 months	14 – 647.2	15 days – 6 months	14 – 647.2
6 months – 1 year	8.4 – 181.9	6 months – 1 year	8.4 – 181.9
1 – 5 years	5.3 – 99.9	1 – 5 years	5.3 – 99.9
5 – 14 years	13.7 – 78.8	5 – 14 years	13.7 – 78.8
14 – 19 years	5.5 – 67.4	14 – 16 years	12.7 – 82.8
		16 – 19 years	11.1 – 171.9

FREE T3 (pg/mL)

AGE	FEMALE	MALE
0 – 1 year	2.32 – 4.87	2.32 – 4.87
1 – 12 years	2.79 – 4.42	2.79 – 4.42
12 – 15 years	2.5 – 3.95	2.89 – 4.33
15 – 19 years	2.31 – 3.71	2.25 – 3.85

FSH (mIU/mL)

AGE	FEMALE	AGE	MALE
0 - 30 days	Not established	0-30 days	Not established
30 days – 1 year	0.4 - 10.4	30 days – 1 year	0.11 – 2.4
1 – 9 years	0.4 – 5.5	1 – 5 years	≤ 0.9
9 – 11 years	0.4 – 4.2	5 – 10 years	≤ 1.6
11 – 19 years	0.3 – 7.8	10 – 13 years	0.4 – 3.9
		13 – 19 years	0.8 - 5.1

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LH (mIU/mL)

AGE	FEMALE	MALE
0 – 4 days	Not established	Not established
4 days – 3 months	≤ 2.4	0.2 – 3.8
3 months – 1 year	≤ 1.2	≤ 2.9
1 – 10 years	≤ 0.3	≤ 0.3
10 – 13 years	≤ 4.3	≤ 4.3
13 – 15 years	0.4 – 6.5	≤ 4.1
15 – 17 years	≤ 13.1	0.8 – 4.8
17 – 19 years	≤ 8.4	0.9 – 7.1

PROGESTERONE (ng/mL)

AGE	FEMALE	MALE
0 – 4 days	Not established	Not established
4 days - 1 year	≤ 1.32	≤ 0.66
1 - 10 years	≤ 0.35	≤ 0.35
10 – 15 years	0.5 - 0.85	0.5 - 0.85
15 - <19 years	0.5 - 10.26	0.5 - 0.57

TOTAL T3 (ng/mL)

AGE	FEMALE	MALE
0 – 4 days	Not established	Not established
4 days - 1 year	0.85 - 2.34	0.85 - 2.34
1 - 12 years	1.13 - 1.89	1.13 - 1.89
12 – 15 years	0.98 - 1.76	0.98 - 1.76
15 - 17 years	0.92 - 1.42	0.94 - 1.56
17 - 19 years	0.90 - 1.68	0.90 - 1.68

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TOTAL T4 (mcg/dL)

AGE	FEMALE	MALE	COMMENT
0 – 7 days	Not established	Not established	Reference range not established for this Abbott Alinity assay for 0- 7 days of age. The reference range for 7d-1yr is: 5.9-13.7 mcg/dL
7 days – 1 year	5.9 – 13.7	5.9 – 13.7	
1 – 9 years	6.2 – 10.3	6.2 – 10.3	
9 – 12 years	5.5 – 9.3	5.5 – 9.3	
12 – 14 years	5.1 – 8.3	5.0 – 8.3	
14 – 19 years	5.5 – 13.0	4.7 – 8.6	

TESTOSTERONE (ng/dL)

AGE	FEMALE	AGE	MALE
0 – 4 days	Not established	0 – 4 days	Not established
4 days - 9 years	4.33 – 62.0	4 days - 6 months	4.33 – 299
9 - 13 years	≤ 28.2	6 months - 9 years	≤ 36
13 – 15 years	10.4 – 44.4	9 – 11 years	≤ 23
15 - 19 years	14.1 - 49.0	11 - 14 years	≤ 444
		14 – 16 years	36 - 632
		16 - 19 years	148 - 794

TSH (mcIU/mL)

AGE	FEMALE/ MALE	COMMENT
0 – 4 days	Not established	Reference range not established for the Abbott Alinity assay for 0- 4 days of age. The reference range for 4 days to < 6 months is: 0.73-4.77 mcIU/mL
4 days – 28 days	0.73 – 4.77	
28 days – 6 months	0.73 – 4.77	
6 months – 14 years	0.7 – 4.17	
14 – 19 years	0.47 – 3.41	

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VITAMIN B12 (pg/mL)

AGE	FEMALE/ MALE
0 – 1 year	259 – 1576
1 – 9 years	283 – 1613
9 – 14 years	252 – 1125
14 – 17 years	244 – 888
17 – 19 years	203 – 811

COMMENTS TO AUTO-APPEND ON PEDIATRIC SAMPLES:

A. Pediatric reference ranges not validated *for this Alinity assay*. For discussion of pediatric reference ranges, see Critical reviews in clinical laboratory science (2017), 54:6,358-413, https://doi.org/10.1080/10408363.2017.1379945

- CA125
- CA 19-9
- CEA
- FOLATE
- INSULIN
- Intact PTH
- Cortisol, Random
- ATPO

B. Pediatric reference ranges not validated for this Alinity assay. For discussion of pediatric reference ranges, see:

1. Critical reviews in clinical laboratory science (2017), 54:6,358-413, https://doi.org/10.1080/10408363.2017.1379945
2. Clin Chem Lab Med (2021), 59(10):1680-87, https://doi.org/10.1515/cclm-2021-0337
    - FREE T4
    - PROLACTIN

C. Pediatric reference ranges not well-established for the Abbott Alinity assay. See references (1,2).

1. Critical reviews in clinical laboratory science (2017), 54:6,358-413, https://doi.org/10.1080/10408363.2017.1379945
2. Clin Chem Lab Med (2021), 59(10):1680-87, https://doi.org/10.1515/cclm-2021-0337
    - HOMOCYSTEINE
    - SHBG