



TOSOH AIA[®] -PACK ANALYTE SUMMARY

Assay Type	Antibody Type	Sample Volume	Assay Sensitivity	Assay Range	Reference Range	Calibrator Values	Standardization
METABOLIC						Liquid (Ready to Use)	
ST CORT (Cortisol)	Competitive	Polyclonal	10 µL	0.2 µg/dL	to 60 µg/dL	AM: 10.4 - 26.4 µg/dL	0, 0.6, 2.0, 6.0, 20.0, 60.0 µg/dL Internal
ST HGH (Human Growth Hormone)	IEMA	Mono-Mono	75 µL	0.07 ng/mL	to 45 ng/mL	Male: ≤5.0 ng/mL, Female: ≤10.0 ng/mL	0, 1.9, 3.8, 11.3, 22.6, 49.7 ng/mL WHO 2nd IS (98/574)
CARDIAC MARKERS							
ST CKMB	IEMA	Mono-Mono	50 µL	0.5 ng/mL	to 500 ng/mL	<5.8 ng/mL	0, 10, 20, 100, 200, 500 ng/mL Internal
ST Myoglobin	IEMA	Mono-Mono	10 µL	2.0 ng/mL	to 1000 ng/mL	11.6 - 73.0 ng/mL	0, 50, 250, 500, 750, 1200 ng/mL Internal
ST cTnl 2nd Gen (Troponin I)	IEMA	Mono-Mono	50 µL	0.06 ng/mL	to 115 ng/mL	Cutoff range is 0.31 - 0.64 ng/mL See Package Insert for more details	0, 0.5, 5, 15, 45, 120 ng/mL Internal
ANEMIA MARKERS							
ST FER (Ferritin)	IEMA	Mono-Mono	20 µL	3.0 ng/mL	to 1000 ng/mL	Males: 18-45 yrs: 22-340 ng/mL, >45 yrs: 22-415 ng/mL Females: 18-45 yrs: 6-115 ng/mL, >45 yrs: 15-200 ng/mL	0, 500 ng/mL WHO 1st IS (80/602)
B12 (Vitamin B12) *	Competitive	Polyclonal	200 µL**	50 pg/mL	to 2000 pg/mL	230 - 1050 pg/mL	0, 100, 250, 500, 1000, 2100 pg/mL Internal
FOL (Folate) *	Competitive	Polyclonal	160 µL**	0.5 ng/mL	to 20 ng/mL	3 - 16 ng/mL	0, 1.0, 2.5, 5.0, 10, 20 ng/mL Internal
RFOL (RBC Folate)*	Competitive	Polyclonal	50 µL**	0.62 ng/mL or 30.3 after final calculation	to 24 ng/mL or 1173 after final calculation	3.4 to 10.3 ng/mL 148.3 to 531.1 ng RBC folate/mL – after final calculation	0, 3.25, 6.5, 13.5, 25, 44 ng/mL Internal
ADDITIONAL ANALYTES							
ST IgE II	IEMA	Mono-Mono	10 µL	3.0 IU/mL	to 4000 IU/mL	5.8 - 216 IU/mL	0, 50, 300, 1000, 2500, 4000 IU/mL WHO 2nd IRP (75/502)
ST PAP (Prostatic Acid Phosphatase)	IEMA	Mono-Mono	75 µL	0.2 ng/mL	to 40 ng/mL	<1.5 ng/mL	0, 20 ng/mL Internal
ST ACTH	IEMA	Polyclonal	50 µL	2.0 pg/mL	to 2000 pg/mL	7.4 - 64.3 pg/mL	0, 15, 50, 300, 800, 2200 pg/mL Internal
ST HCY (Homocysteine)	Competitive	Monoclonal	40 µL**	0.5 µmol/L	to 50 µmol/L	6.6 - 17.8 µmol/L	0, 2, 4, 8, 15, 55 µmol/L Internal
ST Vitamin D*	Competitive	Monoclonal	60 µL**	4.0 ng/mL	120 ng/mL	Deficient: <20 ng/mL, Insufficient: <30 ng/mL Sufficient: 30 - 100 ng/mL, Toxic: >100 ng/mL	0, 10, 20, 40, 80, 165 ng/mL Internal

Notes:

Part# 0080-AA-1115, Lot# 110615

* Not available on the AIA[®]-360

** Sample volume needed for pretreatment;
Off-line pretreatment on the AIA[®]-360

- All AIA[®] -Pack immunoassays are rated as moderately complex according to CLIA complexity rating except for RBC folate which is highly complex.
- All assays have 90-day calibration stability except for B12, Folate and Troponin.
- Specimen type is serum or heparinized plasma except for iPTH which is serum or EDTA plasma and ACTH which is EDTA plasma. Specimen type for RBC Folate is heparin or EDTA whole blood. Specimen type for HbA1c is EDTA whole blood. Specimen type for B12, Folate and TSH3G is serum only.
- Listed calibrator values are approximate; the exact calibrator concentrations are printed on each calibrator vial label.
- Each laboratory should establish or verify its own reference ranges.



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REPRODUCTIVE HORMONES							Liquid (Ready to Use)	
ST βHCG	IEMA	Mono-Mono	50 µL	0.5 mIU/mL	to 400 mIU/mL	<5.0 mIU/mL	0, 200 mIU/mL	WHO 3rd IS (75/537)
ST FSH	IEMA	Mono-Mono	50 µL	1.0 mIU/mL	to 200 mIU/mL	Male: 1.0 - 42.5 mIU/mL Female Ovulating: Follicular Phase: 2.7 - 15.4 mIU/mL Peak: 3.9 - 22.0 mIU/mL, Luteal phase: 1.0 - 14.4 mIU/mL Postmenopausal: 25.0 - 160.0 mIU/mL	0, 100 mIU/mL	WHO 2nd IRP (78/549)
ST LH II	IEMA	Mono-Mono	40 µL	0.2 mIU/mL	to 200 mIU/mL	Male: 1.7 - 11.2 mIU/mL Female Ovulating: Follicular Phase: 1.7 - 13.3 mIU/mL Peak: 4.1 - 68.7 mIU/mL, Luteal phase: 0.5 - 19.8 mIU/mL Postmenopausal: 14.4 - 62.2 mIU/mL	0, 5, 20, 50, 100, 200 mIU/mL	WHO 2nd IS (80/552)
ST PRL (Prolactin)	IEMA	Mono-Mono	30 µL	1.0 ng/mL	to 200 ng/mL	Male: 3.3 - 20.8 ng/mL Female: Premenopausal: 2.1 - 47.6 ng/mL, Postmenopausal: 0 - 41.4 ng/mL	0, 100 ng/mL	WHO 2nd IS (83/562)
ST E2 (Estradiol)	Competitive	Polyclonal	75 µL	25 pg/mL	to 3000 pg/mL	Male: <25 - 75 pg/mL Female Ovulating: Follicular phase: 21.8 – 83.7 pg/mL Peak: 197.6 – 693.1 pg/mL, Luteal phase: 189.9 – 269.7 pg/mL Postmenopausal Female: 32.1 – 73.1 pg/mL	0, 40, 100, 500, 1000, 3200 pg/mL	Internal
ST PROG II (Progesterone)	Competitive	Polyclonal	75 µL	0.1 ng/mL	to 40 ng/mL	Male: ≤1.36 ng/mL Female: Follicular phase: ≤2.05 ng/mL Ovulation phase: ≤19.56 Luteal phase: ≤22.65 ng/mL Postmenopausal: ≤0.48 ng/mL	0, 0.5, 1.5, 5.0, 15.0, 45.0 ng/mL	Internal
ST Testosterone	Competitive	Monoclonal	85 µL	10 ng/dL	to 2200 ng/dL	Male: 199 - 1586 ng/dL Female: 10 - 73.2 ng/dL	0, 30, 100, 350, 900, 2200 ng/dL	Internal
ST DHEA-S	Competitive	Polyclonal	10 µL	2.0 ug/dL	to 1000 ug/dL	Males: < 20 yrs: 35.35 - 819.22 ug/dl, 20-29 yrs: 84.04 - 570.75 ug/dL, 30-39 yrs: 105.9-445.1 ug/dL, 40-49 yrs: 65.7-488.4 ug/dL, 50-59 yrs: 77.4 - 364.8 ug/dL Females: < 20 yrs: 20.91 - 349.95, 20-29 yrs: 50.67 - 413.78 ug/dL, 30-39 yrs: 71.4 - 208.1 ug/dL, 40-49 yrs: 33.8-303.4 ug/dL, 50-59 yrs: 40.8 - 222.0 ug/dL	0, 5, 12, 60, 300, 1200 ug/dL	Internal
ST SHBG	IEMA	Monoclonal	15 µL	0.01 nmol/L or 0.2 nmol/L after dilution factor*	12.5 nmol/L or 250 nmol/L after dilution factor*	Males: 21-49 yrs: 12-64 nmol/L, ≥50 yrs: 18-99 nmol/L** Females (pre-menopausal ≥ 21 years): 19-131 nmol/L** Females (post-menopausal): 15-170 nmol/L**	0, 0.1, 0.3, 1.25, 6.25, 15 nmol/L	2nd IS from NIBSC (Code 08/266)

Notes:

Part# 0080-AA-1115, Lot# 110615

* All samples are diluted 1:20

** See Analyte Application for calculation of free androgen index (%FAI)

- All AIA® -Pack immunoassays are rated as moderately complex according to CLIA complexity rating except for RBC folate which is highly complex.
- All assays have 90-day calibration stability except for B12, Folate and Troponin.
- See other Analyte Summary pages or Analyte Application for specimen type.
- Listed calibrator values are approximate; the exact calibrator concentrations are printed on each calibrator vial label.
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TOSOH AIA® -PACK ANALYTE SUMMARY

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THYROID							Liquid (Ready to Use)		
ST T4	Competitive	Polyclonal	10 µL	0.5 µg/dL	to 24 µg/dL	4.0 - 11.0 µg/dL	0, 0.75, 3, 6, 12, 24 µg/dL	Internal	
ST TT3	Competitive	Monoclonal	25 µL	0.2 ng/mL	to 8 ng/mL	0.7 - 1.7 ng/mL	0, 0.5, 1.0, 2.0, 4.0, 8.0 ng/mL	Internal	
ST TSH	IEMA	Mono-Mono	100 µL	0.03 µIU/mL	to 100 µIU/mL	0.5 - 5.8 µIU/mL 0.6 - 4.8 µIU/mL	No exclusion criteria Excluded samples with a high TPOAb and TgAb	0, 0.2, 5.0, 25, 50, 100 µIU/mL	WHO 2nd IRP (80/558)
TSH3G*	IEMA	Mono-Mono	100 µL	0.01 µIU/mL	to 100 µIU/mL	0.5 - 5.8 µIU/mL 0.6 - 4.8 µIU/mL	No exclusion criteria Excluded samples with a high TPOAb and TgAb	0, 0.2, 5.0, 25, 50, 100 µIU/mL	WHO 2nd IRP (80/558)
ST FT3 (Free T3)	Competitive	Monoclonal	50 µL	0.5 pg/mL	to 25 pg/mL	2.0 - 4.9 pg/mL	0, 1.5, 3.0, 6.0, 12.0, 25 pg/mL	Internal	
ST FT4 (Free T4)	Competitive	Polyclonal	10 µL	0.1 ng/dL	to 8 ng/dL	0.75 - 1.54 ng/dL	0, 0.4, 1.0, 2.5, 4.0, 9.0 ng/dL	Internal	
ST TU (T-Uptake)	Competitive	Polyclonal	10 µL	10 tu	to 60 tu	25 - 38 tu	25, 45 tu	Internal	
TPOAb*	2-step IEMA	TPO Ag-Mono	10 µL	0.16 IU/mL or 8.0 IU/mL after dilution factor**	to 20 IU/mL or 1020 IU/mL after dilution factor**	<10.1 IU/mL	0, 0.5, 2.0, 4, 10, 20 IU/mL	NIBSC (Code 66/387)	
TgAb*	2-step IEMA	Tg Ag-Mono	50 µL	0.24 IU/mL or 12.0 IU/mL after dilution factor**	to 40 IU/mL or 2040 IU/mL after dilution factor**	<28.7 IU/mL	0, 2, 4, 10, 20, 40 IU/mL	NIBSC (Code 65/93)	
DIABETES									
ST C-Peptide II	IEMA	Monoclonal	10 µL	0.04 ng/mL	to 30 ng/mL	Serum: 0.69 – 2.45 ng/mL, Urine: 48 - 100 µg/L	0, 0.5, 2.0, 6.0, 15.0, 33.0 ng/mL	WHO 1st IRP (84/510)	
ST HbA1c****	IEMA	Polyclonal	40 µL***	3.0 %	14.0 %	3.8 - 6.0 %	0, 3.3, 6.3, 9.3, 12.5, 15.5 %	IFCC	
ST IRI (Insulin)	IEMA	Mono-Mono	50 µL	0.5 µU/mL	to 320 µU/mL	<17.0 µU/mL	0, 20, 40, 80, 160, 320 µU/mL	WHO 1st IRP (66/304)	

- * Not available on the AIA®-360
- ** All samples are diluted 1:51
- *** Sample volume needed for hemolysate
- **** Not available on the AIA®-1800 or AIA®-2000

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- Specimen type is serum or heparinized plasma except for iPTH which is serum or EDTA plasma and ACTH which is EDTA plasma. Specimen type for RBC Folate is heparin or EDTA whole blood. Specimen type for HbA1c is EDTA whole blood. Specimen type for B12, Folate and TSH3G is serum only.
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Part# 0080-AA-1115, Lot# 110615



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TUMOR MARKERS							Liquid (Ready to Use)	
ST AFP	IEMA	Mono-Mono	25 µL	1.0 ng/mL	to 400 ng/mL	<5.63 ng/mL	0, 200 ng/mL	WHO 1st IS (72/225)
ST CA 125	IEMA	Mono-Mono	100 µL	2.0 U/mL	to 1000 U/mL	<35 U/mL	0, 10, 30, 125, 500, 1000 U/mL	Internal
ST CA 19-9	IEMA	Mono-Mono	50 µL	1.0 U/mL	to 400 U/mL	<47.0 U/mL See Analyte Application for more details	0, 25, 50, 100, 200, 400 U/mL	Internal
ST 27.29	IEMA	Mono-Mono	20 µL	0.1 U/mL or 2.1 U/mL after dilution factor*	19.05 U/mL or 400 U/mL after dilution factor*	Cutoff is 37.7 U/mL	0, 0.2, 2.5, 5.0, 10, 20 U/mL	Internal
ST CEA	IEMA	Mono-Mono	100 µL	0.5 ng/mL	to 100 ng/mL	Non-Smokers: ≤7.2 ng/mL, Smokers: ≤14.5 ng/mL	0, 50 ng/mL	WHO 1st IRP (73/601)
ST PA (PSA)	IEMA	Mono-Mono	20 µL	0.05 ng/mL	to 100 ng/mL	0 - 4.0 ng/mL	0, 50 ng/mL	Internal
KIDNEY MARKERS								
ST BMG (β ₂ Microglobulin)	IEMA	Mono-Poly	15 µL	0.002 mg/L or 0.102 mg/L after dilution factor**	to 0.4 mg/L or 20.4 mg/L after dilution factor**	Serum: <2.7 mg/L, Urine: <0.3 mg/L	0.0, 0.015, 0.05, 0.15, 0.30, 0.40 mg/L	Internal
ST Cystatin C	IEMA	Mono-Mono	10 µL	0.004 mg/L or 0.1 mg/L after dilution factor***	0.32 mg/L or 8.0 mg/L after dilution factor***	0.50 - 1.16 mg/L	0, 0.01, 0.04, 0.08, 0.16, 0.35 mg/L	Internal
ST iPTH	IEMA	Polyclonal	75 µL	1.0 pg/mL	to 2000 pg/mL	8.2 - 83.5 pg/mL	0, 15, 50, 200, 800, 2200 pg/mL	Internal

Part# 0080-AA-1115, Lot# 110615

- * All samples are diluted 1:21
- ** All samples are diluted 1:51
- *** All samples are diluted 1:25

Notes:

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