

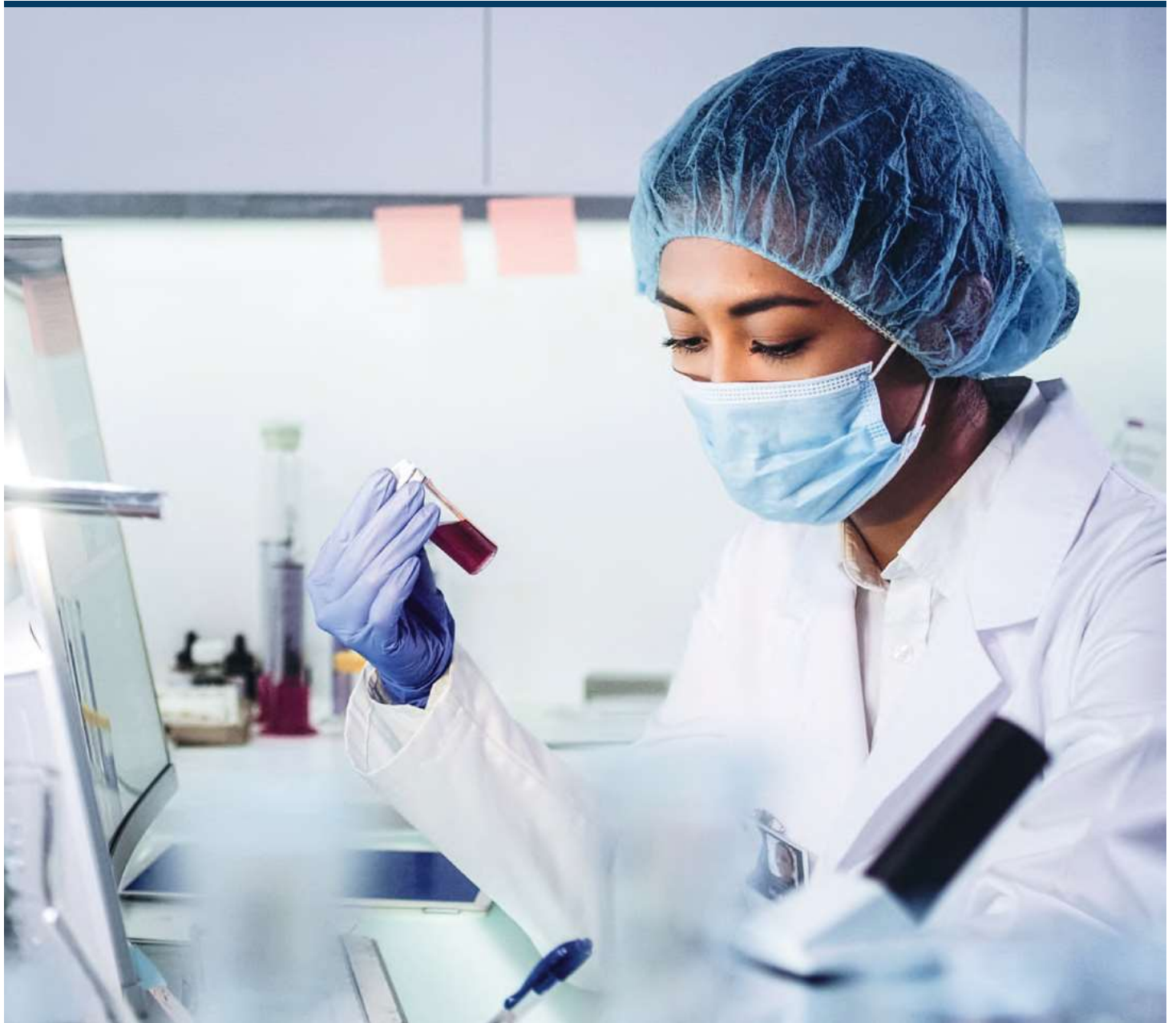
ACCURUN®

Quality Control & Diagnostics
Development Solutions

Distribution Germany and Austria



HiSS
Diagnostics



**Trusted Partner and Global Supplier of Solutions to Diagnostics,
Clinical Research and Life Science Industries for over 30 years**

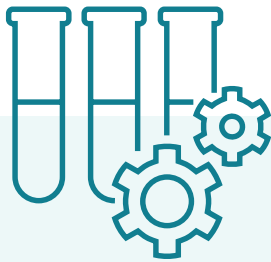


**CLINICAL
DIAGNOSTICS**

sera  **care**

THE BENEFITS OF ACCURUN

- Increase confidence by rigorously challenging your assays
- Mitigate the risk of reporting false results
- Catch declining assay performance in advance of catastrophic failures
- Reduce repeat testing due to errors
- Enhance your assay troubleshooting capabilities
- Improve the monitoring and management of your QC processes



FOUR REASONS NOT TO RELY ON INSTRUMENT MANUFACTURERS' CONTROLS ALONE

1

Manufacturer controls are often formulated from the same raw materials as the assay calibrators, and thus mimic the calibrators' performance.

2

Manufacturer controls are typically high-positive controls, which will not challenge the assay at lower detection limits where the medical decision point lies.

3

Manufacturer in-kit control lot changes tend to be frequent, making long-term monitoring of the assay difficult.

4

In general, manufacturers' controls are optimized for use with the manufacturer's test system, and thus are less likely to identify assay performance issues.

ACCURUN SEROLOGY CONTROLS

- Single and multi-marker independent controls
- Human-sourced controls that mimic true patient samples
- Specifically formulated as low level positive controls
- Ready-to-use liquid; stable at refrigerated temperatures

Avoid false-positives and false-negatives with ACCURUN serological controls in your assay. Our controls help monitor and troubleshoot test methods to isolate system errors in your laboratory. As a leader in lower limit-of-detection controls, we provide the tools to challenge your assay closer to the assay cut-off, giving confidence in your serology test results.



TABLE 1: ACCURUN MULTI-MARKER SEROLOGY CONTROLS

PRODUCT NAME	MARKERS																				COMPLIANCE	STORAGE
	Anti-HAV (Total)	Anti-HAV IgG	Anti-HAV IgM	Anti-HBc (Total)	Anti-HBc IgG	Anti-HBc IgM	Anti-HBe	Anti-HBe	HBsAg	HBsAg	Anti-HCV	Anti-Hepatitis Delta	Anti-HIV 1	Anti-HIV 2	Anti-HIV 1 Ag	Anti-HIV 1	Anti-HIV 2	Anti-HIV 2	Anti-HIV 1	Anti-HIV 2		
MULTI-MARKER POSITIVE	ACCURUN 1 Series 2400		●						●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 1 Series 2500		●						●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD	💧
	ACCURUN 1 Series 4000		●						●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD, US-IVD	💧
	ACCURUN 1 Series 4400		●						●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 1 Series 5600		●						●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 2 Series 2700		●						●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD, CA-IVD	💧
	ACCURUN 21 Series 1000	●							●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD	💧
	ACCURUN 21 Series 2000	●							●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD, CA-IVD	💧
	ACCURUN 21 Series 1000	●							●	●	●	●	●	●	●	●	●	●	●	●	RUO	💧
	ACCURUN 21 Series 2000	●							●	●	●	●	●	●	●	●	●	●	●	●	RUO	💧
	ACCURUN 24								●				●		●						IVD	💧
	Confirmatory Control																					
	ACCURUN 25 ToRCH IgG																				CE-IVD	💧
MULTI-MARKER NEGATIVE	ACCURUN 26 ToRC IgM																				CE-IVD	❄️
	ACCURUN 30																				CE-IVD	❄️
	ACCURUN 40 Series 5000																				CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 51		●																		CE-IVD, US-IVD, CA-IVD	❄️
	ACCURUN 52	●																			CE-IVD, US-IVD, CA-IVD (Pending)	💧
	ACCURUN 1		●																		CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 800 ToRCH										●										CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 810	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	CE-IVD, US-IVD	💧

💧 2 °C – 8 °C

❄️ -20 °C

🧊 -70 °C

SEROLOGY PRODUCT LIST | MULTI-MARKER CONTROLS

Material #	Pack Size	Product Description	Markers	Compliance	Storage
Positive Controls					
2000-0001	12 x 3.5 mL	ACCURUN 1 Series 2400	HIV 1/2, HTLV I/II, HCV, HBsAg, HBc	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2000-0005	6 x 3.5 mL	ACCURUN 1 Series 2700	HIV 1/2, HTLV I/II, HCV, HBsAg, HBc, CMV	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2000-0008	3 x 5.0 mL	ACCURUN 1 Series 4000	HIV 1/2, HTLV I/II, HCV, HBsAg, HBc, CMV	CE-IVD, US-IVD	2 - 8°C
2000-0010	12 x 3.5 mL	ACCURUN 1 Series 4400	HIV 1/2, HTLV I/II, HCV, HBsAg, HBc, CMV	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2000-0018	6 x 3.5 mL	ACCURUN 1 Series 5600	HIV 1/2, HTLV I/II, HCV, HBsAg, HBc, CMV	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2000-0023	6 x 3.5 mL	ACCURUN 2 Series 2700	HIV 1/2, HTLV I/II, HCV, HBsAg, HBc, CMV, Syphilis	CE-IVD, CA-IVD	2 - 8°C
2000-0080	6 x 3.5 mL	ACCURUN 2 Series 2900	HIV 1/2, HTLV I/II, HCV, HBsAg, HBc, CMV, Syphilis	CE-IVD	2 - 8°C
2000-0027	6 x 3.5 mL	ACCURUN 21 Series 1000	HIVC, HBc, HAV, HCV, HBsAg	RUO	2 - 8°C
2000-0028	6 x 3.5 mL	ACCURUN 21 Series 1000	HIVC, HBc, HAV, HCV, HBsAg	CE-IVD	2 - 8°C
2000-0030	6 x 3.5 mL	ACCURUN 21 Series 2000	HIVC, HBc, HAV, HCV, HBsAg	RUO	2 - 8°C
2000-0031	6 x 3.5 mL	ACCURUN 21 Series 2000	HIVC, HBc, HAV, HCV, HBsAg	CE-IVD, CA-IVD	2 - 8°C
2000-0032	3 x 1.0 mL	ACCURUN 24 Series 2000	HIV 1, HIV 2, HTLV I/II, HCV	US-IVD, CA-IVD	2 - 8°C
2000-0034	3 x 1.0 mL	ACCURUN 25 Series 5000	Toxo IgG, Rubella IgG, CMV IgG, HSV 1/2 IgG	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2000-0073	3 x 1.0 mL	ACCURUN 25 Series 1000	Toxo IgG, Rubella IgG, CMV IgG, HSV 1/2 IgG	US-IVD	2 - 8°C
2000-0074	3 x 1.0 mL	ACCURUN 25 Series 2000	Toxo IgG, Rubella IgG, CMV IgG, HSV 1/2 IgG	CE-IVD, CA-IVD	2 - 8°C
2000-0035	3 x 1.0 mL	ACCURUN 26 Series 5000	Toxo IgM, Rubella IgM, CMV IgM	CE-IVD, US-IVD, CA-IVD	-20°C
2000-0037	3 x 1.0 mL	ACCURUN 30	EBV VCA IgG, EBNA IgG	CE-IVD, US-IVD, CA-IVD	-20°C
2000-0038	3 x 1.0 mL	ACCURUN 31	EBV VCA IgM, EBNA IgM	CE-IVD, US-IVD, CA-IVD	-20°C
2000-0039	3 x 1.0 mL	ACCURUN 40 Series 5000	Measles IgG, Mumps IgG, Rubella IgG, VZV IgG	CE-IVD, US-IVD, CA-IVD	2-8°C
2000-0041	6 x 3.5 mL	ACCURUN 51	HBeAg, HBc IgM, HAV IgM	CE-IVD, US-IVD, CA-IVD	-20°C
2000-0063	6 x 3.5 mL	ACCURUN 51 Series 2000	HBeAg, HBc IgM, HAV IgM	US-IVD	-20°C
2000-0067	6 x 3.5 mL	ACCURUN 51 Series 3000	HBeAg, HBc IgM, HAV IgM		-20°C
2000-0043	6 x 3.5 mL	ACCURUN 52	anti-HBe, anti-HBs, anti-HAV IgG	CE-IVD, US-IVD, CA-IVD (Pending)	2 - 8°C
2000-0071	6 x 3.5 mL	ACCURUN 52 Series 3000	anti-HBe, anti-HBs, anti-HAV IgG	CE-IVD, US-IVD, CA-IVD	2 - 8°C
Negative Controls					
2010-0013	1 x 5.0 mL	ACCURUN 1 Multi-Marker Negative	HBsAg, HIV-1 Ag, HIV 1/2, HTLV I/II, HBcAg, HCV, CMV, Syphilis	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2010-0015	12 x 3.5 mL				
2010-0018	1 x 1.0 mL	ACCURUN 800 ToRCH Negative	Toxo IgG, Toxo IgM, Rubella IgG, Rubella IgM, CMV IgG, CMV IgM, HSV 1/2 IgG, HSV 1/2 IgM	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2010-0020	6 x 3.5 mL	ACCURUN 810 Negative	HBsAg, HBeAg, anti-HBs, anti-HBc, anti-HBc IgM, anti-HBe, anti-HCV, anti-HAV, anti-HAV IgM, anti-CMV, Syphilis RPR, Syphilis ATA, HIV 1/2, HTLV I/II, Lyme IgG and Lyme IgM	CE-IVD, US-IVD	2 - 8°C

TABLE 2: ACCURUN SINGLE MARKER SEROLOGY CONTROLS

PRODUCT NAME	MARKERS		MULTI-MARKER POSITIVE																												COMPLIANCE	STORAGE							
	Anti-HAV (Total)	Anti-HAV IgG	Anti-HAV IgM	Anti-HBc (Total)	Anti-HBc IgG	Anti-HBc IgM	Anti-HBe	Anti-HBs	HBeAg	HBsAg	Anti-HCV	Anti-Hepatitis Delta	Anti-HIV 1	Anti-HIV 2	Anti-HIV 1 Ag	Anti-HTLV 1	Anti-HTLV 2	Anti-CMV (Total)	Anti-CMV IgG	Anti-CMV IgM	Anti-HSV 1/2 IgG	Anti-HSV 1/2 IgM	Anti-Mumps IgG	Anti-Rubella IgG	Anti-Rubella IgM	Anti-Toxoplasma IgG	Anti-Toxoplasma IgM	Anti-VZV IgG	Anti-EBNA IgG	Anti-EBV VCA IgG			Anti-EBV VCA IgM	Anti-Lyme IgG	Anti-Lyme IgM	Syphilis (RPR)	Syphilis (Anti-Treponema pallidum)	Anti-Typanosoma cruzi (Chagas)	
ACCURUN 31																																						CE-IVD	❄️
ACCURUN 106 Series 1000																																						CE-IVD	💧
ACCURUN 113																																						CE-IVD, US-IVD, CA-IVD	💧
ACCURUN 115																																						CE-IVD, US-IVD, CA-IVD	💧
ACCURUN 117																																						US-IVD, CE-IVD	❄️
ACCURUN 119																																						US-IVD, CE-IVD	❄️
ACCURUN 120																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 121																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 125																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 127																																						US-IVD, CE-IVD	💧
ACCURUN 130																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 132																																						US-IVD, CA-IVD, CE-IVD	❄️
ACCURUN 135																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 136																																						US-IVD, CA-IVD, CE-IVD	❄️
ACCURUN 140																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 141																																						US-IVD, CA-IVD, CE-IVD	❄️
ACCURUN 145																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 146																																						US-IVD, CA-IVD, CE-IVD	❄️
ACCURUN 155 Series 2000																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 155 Series 5000																																						US-IVD, CA-IVD, CE-IVD	💧
ACCURUN 156																																						US-IVD, CA-IVD, CE-IVD	❄️
ACCURUN 190																																						US-IVD, CE-IVD	💧

💧 2 °C – 8 °C

❄️ -20 °C

🧊 -70 °C

SEROLOGY PRODUCT LIST | SINGLE-MARKER POSITIVE CONTROLS

Material #	Pack Size	Product Description	Markers	Compliance	Storage
2015-0065	3 x 5.0 mL	ACCURUN 106	HIV-1 Ag	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2015-0066	12 x 3.5 mL				
2015-0068	1 x 5.0 mL	ACCURUN 113	HBc IgM	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2015-0070	1 x 5.0 mL	ACCURUN 115	HBc IgG	CE-IVD, US-IVD, CA-IVD	2 - 8°C
2015-0071	1 x 5.0 mL	ACCURUN 117	HBeAg	US-IVD, CE-IVD	-20°C
2015-0072	1 x 5.0 mL	ACCURUN 119	Anti-HBe	US-IVD, CE-IVD	-20°C
2015-0073	1 x 5.0 mL	ACCURUN 120	HAV IgG	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0074	1 x 5.0 mL	ACCURUN 121	HAV IgM	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0076	6 x 3.5 mL				
2015-0077	1 x 5.0 mL	ACCURUN 125	Anti-HBs	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0078	6 x 3.5 mL				
2015-0079	1 x 1.0 mL	ACCURUN 127	Anti-Hepatitis Delta	US-IVD, CE-IVD	2 - 8°C
2015-0080	1 x 1.0 mL	ACCURUN 130	Lyme IgG	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0081	1 x 1.0 mL	ACCURUN 132	Lyme IgM	US-IVD, CA-IVD, CE-IVD	-20°C
2015-0082	1 x 1.0 mL	ACCURUN 135	Toxo IgG	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0083	1 x 1.0 mL	ACCURUN 136	Toxo IgM	US-IVD, CA-IVD, CE-IVD	-20°C
2015-0084	1 x 5.0 mL	ACCURUN 140	Rubella IgG	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0086	1 x 1.0 mL	ACCURUN 141	Rubella IgM	US-IVD, CA-IVD, CE-IVD	-20°C
2015-0087	1 x 1.0 mL	ACCURUN 145	CMV IgG	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0088	1 x 1.0 mL	ACCURUN 146	CMV IgM	US-IVD, CA-IVD, CE-IVD	-20°C
2015-0090	3 x 2.0 mL	ACCURUN 155 Series 2000	Syphilis IgG	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0092	12 x 3.5 mL	ACCURUN 155 Series 5000	Syphilis IgG	US-IVD, CA-IVD, CE-IVD	2 - 8°C
2015-0093	3 x 2.0 mL				
2015-0094	3 x 1.0 mL	ACCURUN 156	RPR	US-IVD, CA-IVD, CE-IVD	-20°C
2015-0097	6 x 3.5 mL	ACCURUN 190	anti-Chagas	US-IVD, CE-IVD	2 - 8°C
2015-0232	2 x 3 mL	ACCURUN Anti-SARS-CoV-2 IgM Controls Kit	SARS-CoV-2	CE-IVD, US-IVD	2 - 8°C
2015-0222	2 x 3 mL	ACCURUN Anti-SARS-CoV-2 Controls Kit, Series 1000	SARS-CoV-2	CE-IVD, US-IVD	2 - 8°C
2015-0225	2 x 3 mL	ACCURUN Anti-SARS-CoV-2 Controls Kit, Series 2000	SARS-CoV-2	CE-IVD, US-IVD	2 - 8°C

