

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**

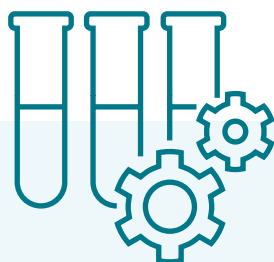


**CLINICAL
DIAGNOSTICS**

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

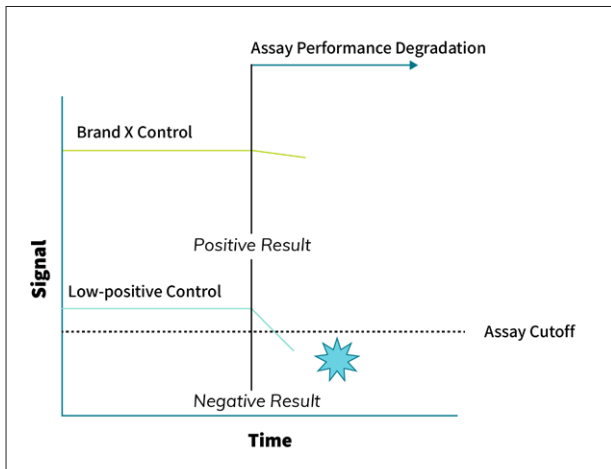
Manufacturer controls are typically high-positive controls, which will not challenge the assay at lower detection limits where the medical decision point lies.

3

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

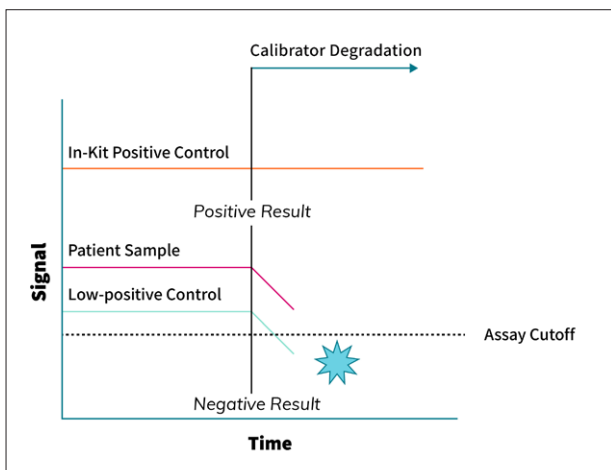
4

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



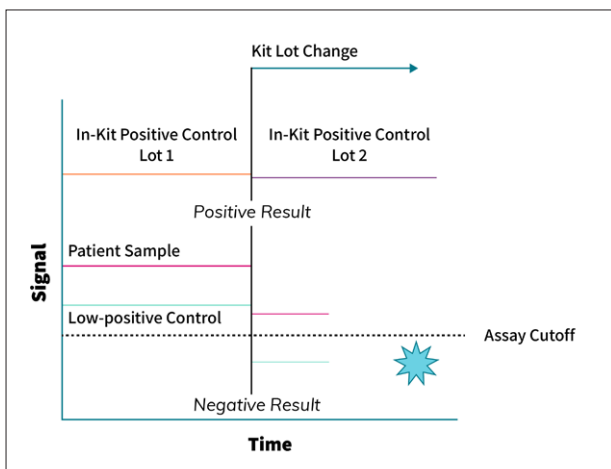
SCENARIO 1

Over time, an assay's performance begins to degrade, resulting in reduced sensitivity to the target analyte. Brand X control was designed with a high analyte concentration; despite the performance degradation, control values do not shift significantly and continue to deliver strong positive results. In contrast, the ACCURUN control — formulated near the clinical cutoff value in a patient-like matrix — exhibits a rapid shift in reported results, drifting toward negative values. This provides advance warning to the lab that there's a problem with the assay.



SCENARIO 2

The calibrator provided in an IVD assay kit has begun to degrade, but this change is not detected by the in-kit positive control, as it was formulated with similar raw materials and designed to work specifically with the manufacturer's assay system; thus, the in-kit control mimics calibrator trends. In contrast, the ACCURUN control immediately identifies the shift in assay performance, alerting lab personnel of a problematic trend that needs to be corrected before patient results are impacted.



SCENARIO 3

A clinical lab has switched to a new lot of a manufacturer's assay kit. The new kit lot exhibits reduced sensitivity, but this change is not detected by the in-kit positive control, as it was used to determine the cutoff value for the new lot. Because the ACCURUN control was independently manufactured and utilized for long term QC monitoring over many assay kit lots, it picks up the significant shift in sensitivity. Without the use of the independent ACCURUN control, patient results may have been compromised.

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 IgM	Anti-HBc (Total)	Anti-HBc IgG	Anti-HBc IgM	Anti-HBe	Anti-HBs	HBeAg	HBsAg	Anti-Hepatitis delta	Anti-HIV 1	Anti-HIV 2	Anti-HIV 1 Ag	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	👉

TABLE 2: ACCURUN SINGLE MARKER SEROLOGY CONTROLS

[illegible]

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

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

ACCURUN MOLECULAR CONTROLS

- Whole-cell or whole-organism third party control
- Mimics a patient sample to monitor entire test performance from extraction to detection
- Weak reactivity to challenge your test performance
- Ready-to-use in various sizes
- Consistency lot-to-lot; large lot size availability



Monitor all aspects of your molecular test with a full-process independent control that truly challenges assay performance. ACCURUN molecular controls mimic patient samples and enable monitoring of the entire testing process, from extraction through detection. As a leader in low-positive controls, we provide the tools to challenge your molecular assay near the limit of detection, enabling superior detection of assay variability.

TABLE 3: ACCURUN MOLECULAR CONTROLS

	PRODUCT NAME	MARKERS										COMPLIANCE	STORAGE
		HBV DNA	HCV RNA	HIV-1 RNA	CT/NG Nucleic Acid	HPV Type 16 DNA	HPV Type 18 DNA	C. difficile	Cystic Fibrosis	Ebola	Zika		
POSITIVE MOLECULAR CONTROLS	ACCURUN 305 Series 100	●										CE-IVD, US-IVD, CA-IVD	🔻
	ACCURUN 305 Series 150	●										CE-IVD, US-IVD, CA-IVD	🔻
	ACCURUN 305 Series 300	●										CE-IVD, US-IVD, CA-IVD	🔻
	ACCURUN 305 Series 400	●										CE-IVD, US-IVD, CA-IVD	🔻
	ACCURUN 315 Series 150		●									CE-IVD, US-IVD, CA-IVD	🔻
	ACCURUN 315 Series 200		●									CE-IVD, US-IVD, CA-IVD	🔻
	ACCURUN 315 Series 400		●									CE-IVD, US-IVD, CA-IVD	🔻
	ACCURUN 325 Series 200	●										CE-IVD, US-IVD, CA-IVD	❄️
	ACCURUN 325 Series 700	●										CE-IVD, US-IVD, CA-IVD	❄️
	ACCURUN 342 Series 100				●							CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 342 Series 700				●							CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 345 Series 150	●	●	●								CE-IVD, US-IVD, CA-IVD	🔻
	ACCURUN 372 Series 400				●							CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 372 Series 600				●							CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 378 Series 5000				●							CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 381				●	●						CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 501						●					CE-IVD, US-IVD, CA-IVD	💧
POSITIVE CONTROLS	ACCURUN 644								●			RUO	❄️
	ACCURUN 676								●			RUO	❄️
NEGATIVE CONTROLS	ACCURUN 803	●	●	●								CE-IVD, US-IVD, CA-IVD	❄️
	ACCURUN 841				●							CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 872				●	●						CE-IVD, US-IVD, CA-IVD	💧
	ACCURUN 873				●	●						CE-IVD, US-IVD, CA-IVD	💧

💧 2 °C – 8 °C

❄️ -20 °C

🔻 -70 °C

ACCURUN POSITIVE MOLECULAR CONTROLS

Material #	Product Name	Markers	# Vials x Fill Size	Compliance
2020-0078	ACCURUN 305 Series 150	HCV RNA	10 x 1.2 mL	US-IVD, CE-IVD, CA-IVD
2020-0080	ACCURUN 305 Series 100	HCV RNA	5 x 1.0 mL	US-IVD, CE-IVD, CA-IVD
2020-0083	ACCURUN 305 Series 300	HCV RNA	5 x 1.0 mL	US-IVD, CE-IVD, CA-IVD
2020-0085	ACCURUN 305 Series 400	HCV RNA	5 x 4.0 mL	US-IVD, CE-IVD, CA-IVD
2020-0087	ACCURUN 315 Series 150	HIV-1 RNA	10 x 1.2 mL	US-IVD, CE-IVD, CA-IVD
2020-0090	ACCURUN 315 Series 200	HIV-1 RNA	5 x 1.0 mL	US-IVD, CE-IVD, CA-IVD
2020-0092	ACCURUN 315 Series 400	HIV-1 RNA	5 x 1.0 mL	US-IVD, CE-IVD, CA-IVD
2020-0096	ACCURUN 325 Series 200	HBV DNA	5 x 4.0 mL	US-IVD, CE-IVD
2020-0098	ACCURUN 325 Series 700	HBV DNA	5 x 4.0 mL	US-IVD, CE-IVD
2025-0067	ACCURUN 342 Series 100	Ct/Ng Nucleic Acid	10 x 1.0 mL	CE-IVD, US-IVD
2025-0068	ACCURUN 342 Series 700	Ct/Ng Nucleic Acid	10 x 1.0 mL	US-IVD, CE-IVD
2020-0104	ACCURUN 345 Series 150	HBV DNA, HCV RNA, HIV-1 RNA	5 x 1.0 mL	US-IVD, CE-IVD, CA-IVD
2020-0105			5 x 4.0 mL	
2025-0037	ACCURUN 372 Series 400	HPV Type 16 DNA	10 x 0.8 mL cell suspension 10 x 2.0 mL diluent	US-IVD, CE-IVD
2025-0041	ACCURUN 372 Series 600	HPV Type 16 DNA	10 x 1.0 mL cell suspension 10 x 1.0 mL diluent	US-IVD, CE-IVD
2025-0043	ACCURUN 378 Series 5000	HPV Type 16 DNA	20 x 4.0 mL	US-IVD, CE-IVD, CA-IVD
2025-0060	ACCURUN 381	HPV Type 16 and 18 mRNA	20 x 1.0 mL	US-IVD, CE-IVD
2050-0008	ACCURUN 501	C. diff – 4 unique strains	4 x 0.6 mL	US-IVD, CE-IVD

ACCURUN NEGATIVE MOLECULAR CONTROLS

Material #	Product Name	Markers	# Vials x Fill Size	Compliance
2035-0007	ACCURUN 803	Negative for HBV DNA, HCV RNA, HIV-1 RNA	10 x 1.2 mL	US-IVD, CE-IVD, CA-IVD
2025-0061	ACCURUN 841	Negative for Ct/Ng	10 x 1.0 mL	US-IVD, CE-IVD
2035-0009	ACCURUN 872	Negative for Type 16 and 18 HPV DNA	10 x 1.0 mL cell suspension 10 x 1.0 mL diluent	US-IVD, CE-IVD
2035-0005	ACCURUN 873	Negative for Type 16 and 18 HPV DNA	20 x 4.0 mL	US-IVD, CE-IVD, CA-IVD

ACCURUN REFERENCE MATERIALS

Material #	Product Name	Markers	# Vials x Fill Size	Compliance
2040-0015	ACCURUN 644	Cystic Fibrosis (47 mutations)	1 x 100 µL	RUO
2040-0009	ACCURUN 676	Cystic Fibrosis (34 mutations)	1 x 100 µL	RUO



**CLINICAL
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HOW TO ORDER:



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