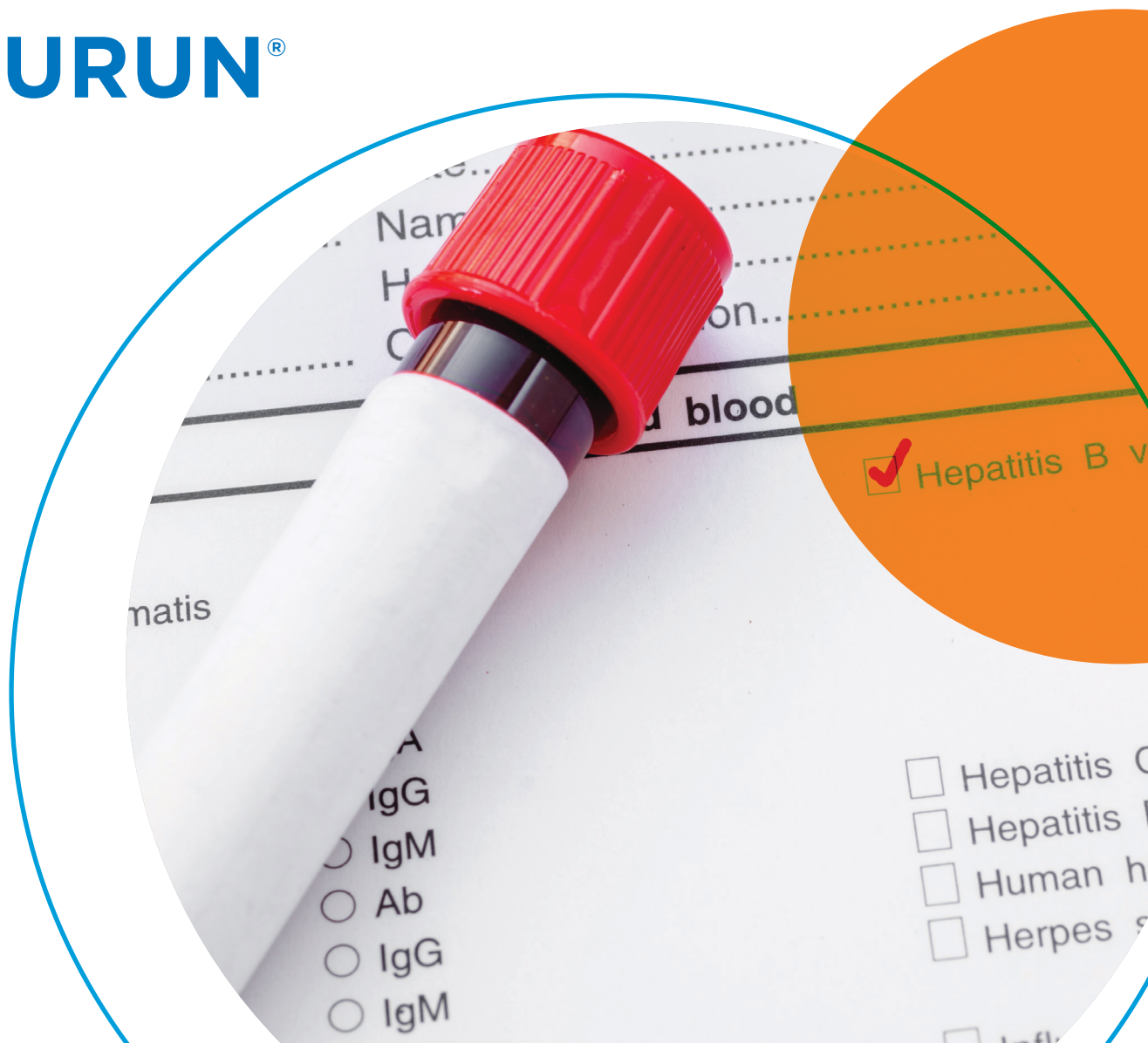




The Leader in Low-Positive Controls

for Infectious
Disease Testing

ACCURUN[®]



Gold Standard Quality Control

Controls and reference materials for infectious disease testing are the cornerstone of SeraCare's QC business. SeraCare has provided gold standard third party run controls and reference materials to clinical laboratories for more than 30 years. This decades-long experience in the manufacture and design of third party controls ensures you're receiving best-in-class products to support clinical lab QC programs, every time.

THE VALUE OF INDEPENDENT CONTROLS

Independent quality controls offer a cost-effective insurance policy against critical testing failures and a costly cycle of troubleshooting, downtime, test repeats, and send outs. Regulatory agencies consider them an essential part of any clinical lab quality control program.

“ **The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.** ”

ISO 15189:2012 5.6.2.1 - Medical Laboratories
- Requirements for quality and competence





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.

THE LEADER IN THIRD PARTY LOW-POSITIVE CONTROLS FOR INFECTIOUS DISEASE

The truest test of an assay's performance is at the lower limits of detection, near the clinical decision point – the boundary between a positive and negative result. This is where even a modest degradation in performance can produce the catastrophic consequence of a false patient result. Unfortunately, many manufacturers' in-kit controls and third party commercial controls are not designed to detect subtle performance changes at these lower detection limits.

SeraCare's ACCURUN controls are specially formulated to exhibit weak reactivity in true patient-like matrices to pressure test assay performance near critical clinical decision points. ACCURUN independent controls offer sensitive detection of subtle shifts in testing trends and mitigate the risk of reporting false results.

QUALITY AND RELIABILITY

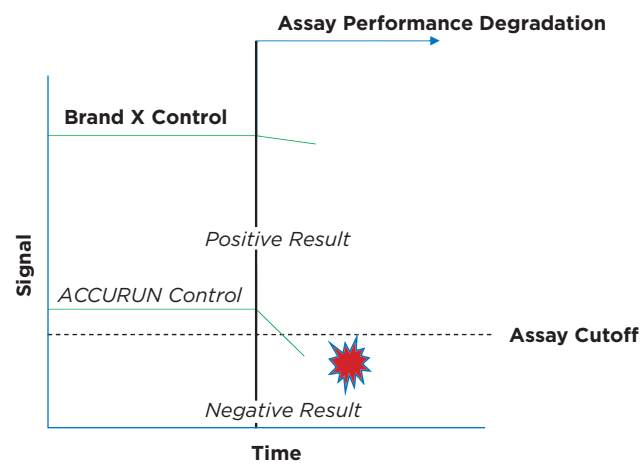
Confidence in your assay results starts with quality controls you can trust. Our facilities are ISO 13485-certified and follow cGMP regulations. This means our products are traceable from sourcing through to delivery – ensuring consistent, high quality QC materials that you can depend on for sensitive daily monitoring of assay performance, providing confidence that reported results are accurate.

“ **Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.** ”

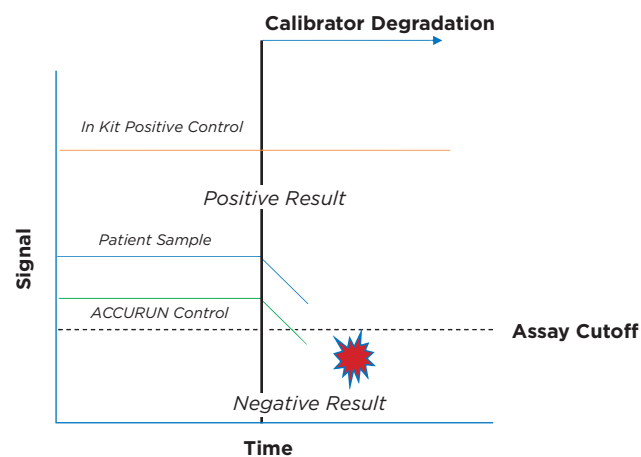
ISO 15189:2012 Section 5.6.2.2 / Medical Laboratories – Requirements for quality and competence

ACCURUN CONTROLS CHECK ALL THE BOXES:

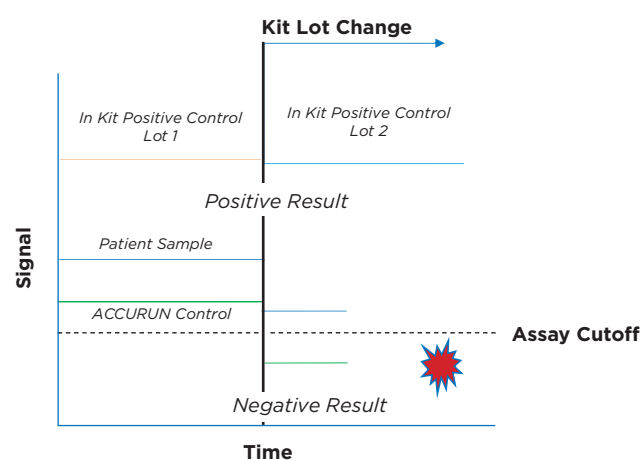
- ✓ **CLINICALLY RELEVANT RANGES:** Specifically designed to be weakly reactive, low-positive controls, ACCURUN truly challenges an assay's performance at critical decision points.
- ✓ **PATIENT-LIKE MATRICES:** ACCURUN controls are formulated to mimic authentic patient samples, as encountered in a daily testing environment.
- ✓ **FULL PROCESS:** Whole virus/organism controls are designed to detect failures at every stage of the testing protocol – from sample prep to detection.
- ✓ **LOT TO LOT CONSISTENCY:** SeraCare produces large lot sizes under cGMP and ISO 13485 conditions. This ensures availability of bulk quantities of a single lot for long-term QC monitoring.
- ✓ **EXTENDED SHELF LIFE:** ACCURUN controls are stable for at least two years from date of manufacture.
- ✓ **OPEN VIAL STABILITY:** Once opened, ACCURUN serology controls are stable for at least 60 days.
- ✓ **EASE OF USE:** Controls are offered in ready-to-use liquid format, enabling streamlined lab workflows.



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 advanced 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 SEROLOGICAL CONTROLS

- Single and multi-analyte 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

ACCURUN SEROLOGICAL CONTROLS

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.

ACCURUN SEROLOGICAL CONTROLS

| PRODUCT NAME | MARKERS | | | | | | | | | | HEPATITIS | | | | | | | | | | HIV/RETROVIRAL | | | | | | | | | | TORCH/MMRV | | | | | | | | | | OTHER | | | | | | | | | |
|---------------------------------|------------------|--------------|------------------|--------------|----------|-------|----------|----------------------|------------|------------|--------------|-------------|-------------|------------------|--------------|------------------|------------------|------------------|---------------------|---------------------|----------------|---------------|------------------|------------------|---------------|----------------|------------------------------------|--------|--|--|------------|--|--|--|--|--|--|--|--|--|-------|--|--|--|--|--|--|--|--|--|
| | Anti-HAV (Total) | Anti-HAV IgM | Anti-HBc (Total) | Anti-HBc IgM | Anti-HBe | HBeAg | Anti-HCV | Anti-Hepatitis Delta | Anti-HIV 1 | Anti-HIV 2 | Anti-HIV 1Ag | Anti-HTLV 1 | Anti-HTLV 2 | Anti-CMV (Total) | Anti-CMV IgM | Anti-HSV 1/2 IgM | Anti-Measles IgG | Anti-Rubella IgG | Anti-Toxoplasma IgM | Anti-Toxoplasma IgG | Anti-VZV IgG | Anti-EBNA IgG | Anti-EBV VCA IgM | Anti-EBV VCA IgG | Anti-Lyme IgM | Syphilis (RPR) | Syphilis (Anti-Treponema pallidum) | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 1 Series 2400 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 1 Series 2500 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 1 Series 4000 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 1 Series 4400 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 1 Series 5600 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 2 Series 2700 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | • | | CE | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 21 Series 1000 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | R | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 21 Series 2000 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | CE | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 21 Series 1000 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | R | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 21 Series 2000 | • | | | | | • | • | • | • | • | • | • | | | | | | | | | | | | | | | CE | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 24 Confirmatory Control | | | | | | | • | | | | • | | | | | | | | | | | | | | | | IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 25 ToRCH IgG | | | | | | | | | | | | | | | • | • | • | • | • | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 26 ToRCH IgM | | | | | | | | | | | | | | | • | | • | • | | | | | | | | | CE IVD | ❄️ | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 30 | | | | | | | | | | | | | | | | | • | | | | • | | | | | | CE IVD | ❄️ | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 40 Series 5000 | | | | | | | | | | | | | | | | • | • | | | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 51 | • | | | | | | | | | | | | | | | | • | | | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 52 | | | | | | | | | | | | | | | | | | | | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 1 | | • | | | | • | • | • | | | • | • | • | | | | | | | | | | | | | • | | CE IVD | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 800 ToRCH | | | | | | | | | | | | | | | • | • | • | • | • | | | | | | | | CE IVD | | | | | | | | | | | | | | | | | | | | | | | |
| ACCURUN 810 | • | • | • | • | • | • | • | • | | | • | • | • | • | • | • | • | • | • | | | | | • | • | • | | CE IVD | | | | | | | | | | | | | | | | | | | | | | |
| MULTI-ANALYTE POSITIVE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| MULTI-ANALYTE NEGATIVE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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- IVDFor In Vitro Diagnostic Use
- RFor Research Use Only

- 2° - 8°C
- ❄️-20°C or colder
- 🌨️-70°C

MULTI-ANALYTE POSITIVE SEROLOGY CONTROLS: See page 12 for detailed ordering information.

NEGATIVE SEROLOGY CONTROLS: See page 13 for detailed ordering information.

| SINGLE ANALYTE POSITIVE | PRODUCT NAME | HEPATITIS | | | | | | | | | | TORCH/MMRV | | | | | | | | | | OTHER | | | | | | | | | |
|-------------------------|-------------------------|------------------|--------------|--------------|------------------|--------------|--------------|----------|-------|----------|----------|----------------------|------------|------------|-------------|-------------|------------------|--------------|------------------|------------------|------------------|---------------------|--------------|---------------|------------------|------------------|---------------|----------------|------------------------------------|--|----|
| | | MARKERS | | | | | | | | | | HIV/RETROVIRAL | | | | | | | | | | COMPLIANCE | | STORAGE | | | | | | | |
| | ACCURUN 31 | Anti-HAV (Total) | Anti-HAV IgG | Anti-HAV IgM | Anti-HBc (Total) | Anti-HBc IgG | Anti-HBc IgM | Anti-HBe | HBeAg | Anti-HBs | Anti-HCV | Anti-Hepatitis Delta | Anti-HIV 1 | Anti-HIV 2 | Anti-HTLV 1 | Anti-HTLV 2 | Anti-CMV (Total) | Anti-CMV IgG | Anti-HSV 1/2 IgM | Anti-Measles IgG | Anti-Rubella IgG | Anti-Tokoplasma IgM | Anti-VZV IgG | Anti-EBNA IgG | Anti-EBV VCA IgG | Anti-EBV VCA IgM | Anti-Lyme IgG | Syphilis (RPR) | Syphilis (Anti-Treponema pallidum) | | |
| | ACCURUN 106 Series 1000 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☃️ |
| | ACCURUN 113 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 115 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 117 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 119 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☃️ |
| | ACCURUN 120 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☃️ |
| | ACCURUN 121 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 125 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 127 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 130 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 132 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☃️ |
| | ACCURUN 135 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 136 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☃️ |
| | ACCURUN 140 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 141 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☃️ |
| | ACCURUN 145 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 146 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☃️ |
| | ACCURUN 155 Series 2000 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 155 Series 5000 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |
| | ACCURUN 156 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☃️ |
| | ACCURUN 190 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☔️ |

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SINGLE ANALYTE POSITIVE SEROLOGY CONTROLS: See pages 12 - 13 for detailed ordering information.



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.

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 | | |
| POSITIVE MOLECULAR CONTROLS | ACCURUN 305 Series 100 | ● | | | | | | | | CE IVD | ⚡ |
| | ACCURUN 305 Series 150 | ● | | | | | | | | CE IVD | ⚡ |
| | ACCURUN 305 Series 300 | ● | | | | | | | | CE IVD | ⚡ |
| | ACCURUN 305 Series 400 | ● | | | | | | | | CE IVD | ⚡ |
| | ACCURUN 306 Series 500 | ● | | | | | | | | R | ⚡ |
| | ACCURUN 315 Series 150 | | ● | | | | | | | CE IVD | ⚡ |
| | ACCURUN 315 Series 200 | | ● | | | | | | | CE IVD | ⚡ |
| | ACCURUN 315 Series 400 | | ● | | | | | | | CE IVD | ⚡ |
| | ACCURUN 315 Series 500 | | ● | | | | | | | CE IVD | ⚡ |
| | ACCURUN 325 Series 200 | ● | | | | | | | | CE IVD | ❄ |
| | ACCURUN 325 Series 700 | ● | | | | | | | | CE IVD | ❄ |
| | ACCURUN 342 Series 100 | | | | ● | | | | | CE IVD | 💧 |
| | ACCURUN 342 Series 700 | | | | ● | | | | | CE IVD | 💧 |
| | ACCURUN 345 Series 150 | ● | ● | ● | | | | | | CE IVD | ⚡ |
| | ACCURUN 372 Series 400 | | | | ● | | | | | CE IVD | 💧 |
| | ACCURUN 372 Series 600 | | | | ● | | | | | CE IVD | 💧 |
| | ACCURUN 378 Series 5000 | | | | ● | | | | | CE IVD | 💧 |
| | ACCURUN 381 | | | | ● | ● | | | | CE IVD | 💧 |
| GENETIC REFERENCE | ACCURUN 501 | | | | | | | ● | | CE IVD | ❄ |
| | ACCURUN 611 | | | | | | | | ● | R | ❄ |
| | ACCURUN 644 | | | | | | | | ● | R | ❄ |
| NEGATIVE CONTROLS | ACCURUN 676 | | | | | | | | ● | R | ❄ |
| | ACCURUN 803 | ● | ● | ● | | | | | | CE IVD | ❄ |
| | ACCURUN 841 | | | | ● | | | | | CE IVD | 💧 |
| | ACCURUN 872 | | | | ● | ● | | | | CE IVD | 💧 |
| | ACCURUN 873 | | | | ● | ● | | | | CE IVD | 💧 |

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- ⚡ | -70°C

POSITIVE MOLECULAR CONTROLS: See page 13-14 for detailed ordering information.
NEGATIVE MOLECULAR CONTROLS: See page 14 for detailed ordering information.
GENETIC REFERENCE MATERIALS: See page 14 for detailed ordering information.



ACCURUN Multi-Analyte Positive Serology Controls

| Material # | Product Name | Markers | # Vials x Fill Size | Compliance |
|------------|---------------------------------|---|---------------------|-------------|
| 2000-0001 | ACCURUN 1 Series 2400 | Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, Anti-HTLV-I, Anti-HTLV-II, HBsAg | 12 x 3.5 mL | IVD, CE, HC |
| 2000-0002 | ACCURUN 1 Series 2500 | | | |
| 2000-0008 | ACCURUN 1 Series 4000 | | 3 x 5.0 mL | |
| 2000-0010 | ACCURUN 1 Series 4400 | Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, Anti-HTLV-I, Anti-HTLV-II, HBsAg, Anti-CMV | 12 x 3.5 mL | IVD, CE, HC |
| 2000-0018 | ACCURUN 1 Series 5600 | | 6 x 3.5 mL | |
| 2000-0023 | ACCURUN 2 Series 2700 | Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, Anti-HTLV-I, Anti-HTLV-II, HBsAg, Anti-CMV, Anti-Treponema pallidum | 6 x 3.5 mL | CE |
| 2000-0027 | ACCURUN 21 Series 1000 | Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, HBsAg, Anti-HAV | 6 x 3.5 mL | RUO |
| 2000-0028 | ACCURUN 21 Series 1000 | Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, HBsAg, Anti-HAV | 6 x 3.5 mL | CE, HC |
| 2000-0030 | ACCURUN 21 Series 2000 | Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, HBsAg, Anti-HAV | 6 x 3.5 mL | RUO |
| 2000-0031 | ACCURUN 21 Series 2000 | Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, HBsAg, Anti-HAV | 6 x 3.5 mL | CE, HC |
| 2000-0032 | ACCURUN 24 Confirmatory Control | Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HTLV-I, Anti-HTLV-II | 3 x 1.0 mL | IVD, HC |
| 2000-0034 | ACCURUN 25 ToRCH IgG | Anti-Toxoplasma IgG, Anti-Rubella IgG, Anti-CMV IgG, Anti-HSV IgG | 3 x 1.0 mL | IVD, CE, HC |
| 2000-0035 | ACCURUN 26 ToRC IgM | Anti-Toxoplasma IgM, Anti-Rubella IgM, Anti-CMV IgM | 3 x 1.0 mL | IVD, CE, HC |
| 2000-0037 | ACCURUN 30 | EBV VCA IgG, EBNA IgG | 3 x 1.0 mL | IVD, CE, HC |
| 2000-0039 | ACCURUN 40 Series 5000 | Anti-Measles, Anti-Mumps, Anti-Rubella, Anti-VZV | 3 x 1.0 mL | IVD, CE, HC |
| 2000-0040 | ACCURUN 51 | HBeAg, HBc IgM, HAV IgM | 1 x 5.0 mL | IVD, CE, HC |
| 2000-0041 | | | 6 x 3.5 mL | |
| 2000-0043 | ACCURUN 52 | Anti-HBe, Anti-HBs, Anti-HAV | 6 x 3.5 mL | IVD, CE, HC |

ACCURUN Single-Analyte Positive Serology Controls

| Material # | Product Name | Markers | # Vials x Fill Size | Compliance |
|------------|--------------------------|----------------------|---------------------|-------------|
| 2000-0038 | ACCURUN 31 | EBV VCA IgM | 3 x 1.0 mL | IVD, CE, HC |
| 2015-0065 | ACCURUN 106, Series 1000 | HIV-1 Ag | 3 x 5.0 mL | IVD, CE, HC |
| 2015-0066 | | | 12 x 3.5 mL | |
| 2015-0068 | ACCURUN 113 | HBc IgM | 1 x 5.0 mL | IVD, CE, HC |
| 2015-0070 | ACCURUN 115 | HBc IgG | 1 x 5.0 mL | IVD, CE, HC |
| 2015-0071 | ACCURUN 117 | HBeAg | 1 x 5.0 mL | IVD, CE |
| 2015-0072 | ACCURUN 119 | Anti-HBe | 1 x 5.0 mL | IVD, CE |
| 2015-0073 | ACCURUN 120 | HAV IgG | 1 x 5.0 mL | IVD, CE, HC |
| 2015-0074 | ACCURUN 121 | HAV IgM | 1 x 5.0 mL | IVD, CE, HC |
| 2015-0076 | | | 6 x 3.5 mL | |
| 2015-0077 | ACCURUN 125 | Anti-HBs | 1 x 5.0 mL | IVD, CE, HC |
| 2015-0078 | | | 6 x 3.5 mL | |
| 2015-0079 | ACCURUN 127 | Anti-Hepatitis Delta | 1 x 1.0 mL | IVD, CE |
| 2015-0080 | ACCURUN 130 | Lyme IgG | 1 x 1.0 mL | IVD, CE, HC |
| 2015-0081 | ACCURUN 132 | Lyme IgM | 1 x 1.0 mL | IVD, CE, HC |

ACCURUN Single-Analyte Positive Serology Controls (continued)

| Material # | Product Name | Markers | # Vials x Fill Size | Compliance |
|------------|-------------------------|-----------------------------------|---------------------|-------------|
| 2015-0082 | ACCURUN 135 | Anti-Toxoplasma IgG | 1 x 1.0 mL | IVD, CE, HC |
| 2015-0083 | ACCURUN 136 | Anti-Toxoplasma IgM | 1 x 1.0 mL | IVD, CE, HC |
| 2015-0084 | ACCURUN 140 | Rubella IgG | 1 x 5.0 mL | IVD, CE, HC |
| 2015-0086 | ACCURUN 141 | Rubella IgM | 1 x 1.0 mL | IVD, CE, HC |
| 2015-0087 | ACCURUN 145 | CMV IgG | 1 x 1.0 mL | IVD, CE, HC |
| 2015-0088 | ACCURUN 146 | CMV IgM | 1 x 1.0 mL | IVD, CE, HC |
| 2015-0090 | ACCURUN 155 Series 2000 | Syphilis (Treponema pallidum) IgG | 3 x 2.0 mL | IVD, CE, HC |
| 2015-0092 | ACCURUN 155 Series 5000 | Syphilis (Treponema pallidum) IgG | 12 x 3.5 mL | IVD, CE, HC |
| 2015-0093 | | | 3 x 2.0 mL | |
| 2015-0094 | ACCURUN 156 | Syphilis (RPR) | 3 x 1.0 mL | IVD, CE, HC |
| 2015-0097 | ACCURUN 190 | Anti-Trypanosoma cruzi (Chagas) | 6 x 3.5 mL | IVD, CE |

ACCURUN Negative Serology Controls

| Material # | Product Name | Markers | # Vials x Fill Size | Compliance |
|------------|-------------------|---|---------------------|-------------|
| 2010-0013 | ACCURUN 1 | Negative for Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, Anti-HTLV-I, Anti-HTLV-II, HBsAg, Anti-CMV, HIV-1 Ag, Anti-Treponema pallidum | 1 x 5.0 mL | IVD, CE, HC |
| 2010-0015 | | | 12 x 3.5 mL | |
| 2010-0018 | ACCURUN 800 ToRCH | Negative for Anti-Toxoplasma, Anti-Rubella, Anti-CMV, Anti-HCV, Anti-HIV-1, Anti-HIV-2, Anti-HSV, Anti-HTLV, and HBsAg | 1 x 1.0 mL | IVD, CE, HC |
| 2010-0020 | ACCURUN 810 | Negative for Anti-HIV-1, Anti-HIV-2, Anti-HCV, Anti-HBc, Anti-HTLV-I, Anti-HTLV-II, Anti-CMV, Anti-HBe, Anti-HBs, Anti-HAV, HAV IgM, HBc IgM, HBeAg, HBsAg, Anti-Treponema pallidum, Syphilis RPR, Lyme IgG, Lyme IgM | 6 x 3.5 mL | IVD, CE, HC |

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 | IVD, CE, HC |
| 2020-0080 | ACCURUN 305 Series 100 | HCV RNA | 5 x 1.0 mL | IVD, CE, HC |
| 2020-0083 | ACCURUN 305 Series 300 | HCV RNA | 5 x 1.0 mL | IVD, CE, HC |
| 2020-0085 | ACCURUN 305 Series 400 | HCV RNA | 5 x 4.0 mL | IVD, CE, HC |
| 2020-0086 | ACCURUN 306 Series 500 | HCV RNA | 10 x 0.5 mL | RUO |
| 2020-0087 | ACCURUN 315 Series 150 | HIV-1 RNA | 10 x 1.2 mL | IVD, CE, HC |
| 2020-0090 | ACCURUN 315 Series 200 | HIV-1 RNA | 5 x 1.0 mL | IVD, CE, HC |
| 2020-0092 | ACCURUN 315 Series 400 | HIV-1 RNA | 5 x 1.0 mL | IVD, CE, HC |
| 2020-0093 | ACCURUN 315 Series 500 | HIV-1 RNA | 5 x 1.0 mL | IVD, CE, HC |
| 2020-0096 | ACCURUN 325 Series 200 | HBV DNA | 5 x 4.0 mL | IVD, CE |
| 2020-0098 | ACCURUN 325 Series 700 | HBV DNA | 5 x 4.0 mL | IVD, CE |
| 2025-0067 | ACCURUN 342 Series 100 | Ct/Ng Nucleic Acid | 10 x 1.0 mL | IVD, CE |
| 2025-0068 | ACCURUN 342 Series 700 | Ct/Ng Nucleic Acid | 10 x 1.0 mL | IVD, CE |

ACCURUN Positive Molecular Controls (continued)

| Material # | Product Name | Markers | # Vials x Fill Size | Compliance |
|------------|-------------------------|-----------------------------|--|-------------|
| 2020-0104 | ACCURUN 345 Series 150 | HBV DNA, HCV RNA, HIV-1 RNA | 5 x 1.0 mL | IVD, CE, HC |
| 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 | IVD, CE |
| 2025-0041 | ACCURUN 372 Series 600 | HPV Type 16 DNA | 10 x 1.0 mL cell suspension 10 x 1.0 mL diluent | IVD, CE |
| 2025-0043 | ACCURUN 378 Series 5000 | HPV Type 16 DNA | 20 x 4.0 mL | IVD, CE, HC |
| 2025-0060 | ACCURUN 381 | HPV Type 16 and 18 mRNA | 20 x 1.0 mL | IVD, CE |
| 2050-0008 | ACCURUN 501 | C. diff – 4 unique strains | 4 x 0.6 mL | IVD, CE |

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 | IVD, CE, HC |
| 2025-0061 | ACCURUN 841 | Negative for Ct/Ng | 10 x 1.0 mL | IVD, CE |
| 2035-0009 | ACCURUN 872 | Negative for HPV DNA | 10 x 1.0 mL cell suspension 10 x 1.0 mL diluent | IVD, CE |
| 2035-0005 | ACCURUN 873 | Negative for HPV DNA | 20 x 4.0 mL | IVD, CE, HC |


ACCURUN Genetic Reference Materials


| Material # | Product Name | Markers | # Vials x Fill Size | Compliance |
|------------|--------------|--------------------------------|---------------------|------------|
| 2040-0038 | ACCURUN 611 | Factor II, Factor V, and MTHFR | 20 x 10 µL | RUO |
| 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 |





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