

Award-winning diagnostic solutions



The SmartSpot patented technology enables the packaging of inactivated specimens on a simple spot on a card, which is easily and safely tested like a patient's clinical specimen.

SMARTSPOT QUALITY IS AN ISO/IEC 17043:2010 ACCREDITED PROFICIENCY TESTING SCHEME PROVIDER



EQA

External Quality Assessment provides on-going quality monitoring of diagnostics, from pre- to post-analytical processing. SmartSpot Quality's EQA Programs run three times per year per instrument.

Internal Controls

Monthly Quality Control (QC) provides performance monitoring of test kits and personnel, four times per month.



Validation

Assay Validation is designed to test Precision and Accuracy of a new assays.

Verification

Instrument verification involves testing standardized material on a diagnostic instrument to ensure that it is 'fit-for-purpose' before clinical specimens can be tested. Verification is recommended upon installation, post-calibration and post-relocation.

Why our programs are industry leading

Controls are stable at ambient temperatures for up to **36 months** reducing shipping by 67% and mitigating the risk of damage to the controls.

In-depth support to laboratories via **video conferencing**, providing technical guidance and general operational advice.







Online Quality Assessment Tool provided for submitting EQA and Verification results and reviewing performance.

14 work days or real-time turnaround for Participant Reports. Group management reports with **analytics and insights**.

Tuberculosis

SmartSpot Quality provides the largest commercially available Molecular *Mycobacterium Tuberculosis* EQA program globally with instruments enrolled across 35 countries.

All controls are non-infectious and stable at ambient temperature for 12-36 months*.

| EQA | Name | Quantity Per Cycle | Catalogue # |
|--|--|---------------------------------|--|
|  | Xpert MTB EQA Program (3 Cycles) | 4 Spots | SSQ-X-MTBRIF-EQA |
|  | Xpert MTB XDR EQA Program (3 Cycles) | 4 Spots | SSQ-X-MTBXDR-EQA |
|  | LPA MTBDRplus EQA Program (3 Cycles) LPA MTBDRsl EQA Program (3 Cycles) | 4 Spots & 5 Strips | SSQ-LPA-MTBDRplus-EQA SSQ-LPA-MTBDRsl-EQA |
|  | Urine TB LF-LAM EQA Program (3 Cycles) (Pilot) | 4 Vials (Not yet accredited) | SSQ-LFLAM-MTB-EQA |
|  | MTBC LAMP EQA Program (3 Cycles) | 4 Spots | SSQ-LAMP-MTBC-EQA |
|  | Truenat MTB RIF EQA Program (3 Cycles) | 4 Spots | SSQ-TN-MTBRIF-EQA |








* Urine TB LF LAM EQA Controls are currently being piloted and stability studies are ongoing.

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Tuberculosis

SmartSpot Quality provides a range of Verification and Validation Panels for TB Diagnostics. For custom requirements, please contact us at info@SmartSpotQ.com.

All controls are non-infectious and stable at ambient temperature for 12-36 months*.

| VERIFICATION | Name | Quantity | Catalogue # |
|--|---|---|------------------------|
|  | Xpert MTB Verification Panel | 1 Spot | SSQ-X-MTBRIF-VRF-1 |
|  | Xpert MTB Verification Panel | 5 Spots | SSQ-X-MTBRIF-VRF-5 |
|  | Xpert MTB Ultra Verification Panel | 4 Spots | SSQ-X-MTBRIF_ULTRA-VRF |
|  | Xpert MTB XDR Validation Panel | 25 Spots | VP-DCS25MTB/XDR |
|  | Xpert MTB XDR Pre-rollout Verification | 4 Spots | SSQ-X-MTBXDR-VRF |
|  | MTBC LAMP Verification Panel | 8 Spots | SSQ-LAMP-MTBC-VRF-8 |
|  | Urine TB LF-LAM Monthly QC (<i>Pilot</i>) | 8 Liquid Specimens (<i>Not yet accredited</i>) | SSQ-LFLAM-MTB-MQC |




SARS-COV-2




PTS 0017

SmartSpot has harnessed its platform in order to respond to the COVID-19 pandemic and provide a set of non-infectious and ambient temperature stable Quality Controls for molecular diagnostic SARS-CoV-2 assays.

The controls contain targets in the N; E; RdRP, Spike and/or ORF1a/b regions and have been validated on the GeneXpert, Thermofisher, Abbott, Roche, Biomerieux, Bioer, Molbio, Bioneer, Biorad, GeneFinder, LineGene and LongGene platforms. For compatibility on alternative instruments, please contact us for more information on info@SmartSpotQ.com


| EQA | Name and Description | Quantity Per Cycle | Catalogue # |
|--|--|--------------------|------------------------------------|
|  | Xpert SARS-CoV-2 EQA Program (3 Cycles) Molecular SARS-CoV-2 EQA Program (3 Cycles) | 4 Spots | SSQ-X-COV2-EQA SSQ-MOL-COV2-EQA |

| VERIFICATION | Name and Description | Quantity | Catalogue # |
|--|-------------------------|----------|------------------|
|  | SARS-CoV-2 Verification | 4 Spots | SSQ-X-COV2-VRF-4 |

SARS-COV-2 & Flu/RSV (Pilot)

SmartSpot has launched a pilot to address customer needs for testing for multiplex testing of SARS-CoV-2 Flu & RSV,

The controls contain targets in the N; E; RdRP, Spike, ORF1a/b, FluA, FluB, RSVA, and/or RSVB regions and have been validated on the GeneXpert. For compatibility on alternative instruments, please contact us for more information on info@SmartSpotQ.com



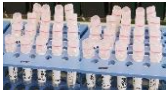



| EQA | Name and Description | Quantity Per Cycle | Catalogue # |
|--|--|---------------------------------|--|
|  | Xpert CoV-2/Flu/RSV EQA Program (3 Cycles) Molecular CoV-2/Flu/RSV EQA Program (3 Cycles) | 4 Spots (Not yet accredited) | SSQ-X-COV2FLURSV-EQA SSQ-MOL-COV2FLURSV-EQA |

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HIV

SmartSpot Quality provides the first non-infectious liquid Human Immuno-deficiency Virus EQA and Verification Control Program that is stable at ambient temperature.



The controls are compatible with Viral Load and Qualitative (EID - Early Infant Diagnosis) testing on the following platforms: Abbott; Roche; Xpert; Hologic and Biocentric. HIV Qualitative controls are also available in Dry Blood Spot (DBS) format.



| EQA | Name and Description | Quantity | Catalogue # |
|--|--|----------|--|
|  | Xpert HIV-1 Viral Load EQA Panel Molecular HIV-1 Viral Load EQA Panel | 4 Vials | SSQ-X-HIV_VL-EQA SSQ-MOL-HIV_VL-EQA |
|  | Xpert HIV-1 Qual and XC EQA Panel Molecular HIV Qual EQA Panel | 4 DBS | SSQ-X-HIV_QUALXC-EQA SSQ-MOL-HIV_QUAL-EQA |
| VERIFICATION | Name and Description | Quantity | Catalogue # |
|  | Validation Panel - High Throughput VL | 42 Vials | SSQ-MOL-HIV_VL-VAL |
| | Validation Panel - Precision Study - Xpert VL | 24 Vials | |
| | Validation Panel - Accuracy Study - Xpert VL | 10 Vials | |
| | Validation Panel - m-Pima VL | 16 Vials | |
|  | Validation Panel - High Throughput Qual | 42 Vials | SSQ-MOL-HIV_VL-VAL |
| | Validation Panel - Precision Study - Xpert Qual | 24 Vials | |
| | Validation Panel - Accuracy Study - Xpert Qual | 10 Vials | |
| | Validation Panel - m-Pima Detect | 16 Vials | |
|  | HIV Viral Load Verification (Low – High Throughput) | 12 Vials | SSQ-X-HIV_VL-VRF-3x4 SSQ-X-HIV_QualXC-VRF-3x4 |
| | HIV Qual Verification (Low – High Throughput) | 12 Vials | |
| | HIV Viral Load Verification (Single module) | 6 Vials | |
| | HIV Qual Verification (Single module) | 6 Vials | |
|  | HIV Qual Validation – Precision Study - DBS | 16 DBS | SSQ-X-HIV_QUALXC-VRF-3x4DBS |
| | HIV Qual Verification - DBS | 12 DBS | |

Viral Hepatitis (Pilot)



SmartSpot Quality provides a non-infectious liquid Human Viral Hepatitis EQA and Verification Control Program that is stable at ambient temperature.

The controls are compatible with Viral Load testing on the following platforms: Abbott; Roche; Xpert; Hologic and Biocentric.

| EQA | Name and Description | Quantity | Catalogue # |
|--|--|----------|--|
|  | Xpert HCV Viral Load EQA Panel Molecular HCV Viral Load EQA Panel | 4 Vials | SSQ-X-HCV_VL-EQA SSQ-MOL-HCV_VL-EQA |
|  | Xpert HBV Viral Load EQA Panel Molecular HBV Viral Load EQA Panel | 4 Vials | SSQ-X-HBV_VL-EQA SSQ-MOL-HBV_VL-EQA |

| VERIFICATION | Name and Description | Quantity | Catalogue # |
|--|--|----------|----------------------|
|  | HCV Viral Load Verification 12 specimen (3 specimens tested per module) | 12 Vials | SSQ-X-HCV_VL-VRF-3x4 |
|  | HBV Viral Load Verification 12 specimen (3 specimens tested per module) | 12 Vials | SSQ-X-HBV_VL-VRF-3x4 |

Human Papilloma Virus (Pilot)

| EQA and VERIFICATION | Name and Description | Quantity | Catalogue # |
|--|--|----------|-------------------|
|  | HPV Viral Load EQA Panel | 4 Vials | SSQ-X-HPV_LIQ |
|  | HPV Viral Load Verification 12 specimen (3 specimens tested per module) | 12 Vials | SSQ-X-HPV_VRF-3x4 |

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