EQA & VERIFICATION
Fact Sheets

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

PTS 0017

SMARTSPOT QUALITY

MDR TB Quality Controls

Scan for Catalogue

SmartSpot Quality offers a range of Quality Control Panels for MDR TB diagnostics

ISO/IEC 17043:2010 Accredited

Each panel consists of a combination of **MTB** (**RIF** sensitive, RIF resistant, **INH** sensitive, INH resistant), Non-Tuberculosis Mycobacteria (**NTM**) and/or MTB negative material – all of which is **inactivated**, quantified and intact.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Pre-Rollout Verification: A single occasion exercise designed to verify software, instrument and user training prior to commissioning the use of a new assay.

Post-Contam Verification: In cases where contamination was identified, this Single Occasion Exercise is designed to verify that the decontamination was successful in removing even trace amounts of contamination.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for **36 months** reducing shipping cost by 67% and mitigating the risk of damage to the controls.
- Online Quality Assessment Tool provided for submitting results and reviewing performance.
- In-depth support to laboratories via video conferencing, providing technical guidance and general operational advice.
- Group Management Reports with analytics and insights for managers of institutions.

Special feature of the Xpert MTB/RIF Ultra Program:

EQA and Verification panels include a Trace specific positive control.

Special feature of the GenoType MTBDR*plus* Program:

SmartSpot gives recognition to sites that strive to continually challenge and improve their interpretation skills, by awarding **Area of Excellence** status for the correct determination of:

- **NTM Classifications** for MTB Negative specimens
- **Hetero-Resistance** to antibiotics
- **Inferred Resistance** to antibiotics
- The **Level of Isoniazid** Resistance
- SmartSpot's **Challenge Strip**

Assay	QC Panel	Panel Constituents
Xpert MTB/RIF	Verification EQA	8 Specimens 4 Specimens / 3x year
Xpert MTB/RIF Ultra Truenat MTB and MTB-RIF	Post-contam Verification Pre-rollout Verification EQA	4 Specimens 4 Specimens 4 Specimens / 3x year
MTBC LAMP	Verification EQA	8 Specimens 4 Specimens / 3x year
GenoType MTBDR*plus and CM* Assay	EQA	4 Specimens & 5 Digital Strip Images / 3x year
Determine TB LAM Ag	Verification EQA	8 Specimens 4 Specimens / 3x year
TB NGS & WGS (Pilot)	Verification EQA	8 Specimens 4 Specimens / 3x year

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SMARTSPOT QUALITY

XDR TB Quality Controls

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SmartSpot Quality offers a range of Quality Control Panels for XDR TB diagnostics:

ISO/IEC 17043:2010 Accredited

Each panel consists of a combination of **non-infectious**, quantified and intact **MTB Positive** and Non-tuberculosis mycobacteria (**NTM**) or MTB negative specimens. The MTB Positive specimens have varying **multi-resistance** and **pan-resistant** profiles.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

Controls are stable at ambient temperatures for 18 months reducing shipping cost 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 results and reviewing performance.

Group Management Reports with analytics and insights for managers of institutions.

Validation: A single occasion exercise designed to test Reproducibility of a new assay across Wild Type and Mutant MTB strains.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Special feature of the Xpert MTB/XDR Program:

SmartSpot's XDR controls are all non-infectious and contain a broad set of mutations so as to test the Xpert MTB/XDR assay widely.

Special feature of the LPA GenoType MTBDR*sl* Program:

SmartSpot gives recognition to sites that strive to continually challenge and improve their interpretation skills, by awarding **Area of Excellence** status for the correct determination of:

- **Hetero-Resistance** to antibiotics
- **Inferred Resistance** to antibiotics
- SmartSpot's **Challenge Strip**

Assay	QC Panel	Panel Constituents
Xpert MTB/XDR	Validation Verification EQA	25 Specimens 12 Specimens 4 Specimens / 3x year
LPA GenoType MTBDR*sl*	EQA	4 Specimens & 5 Digital Strip Images / 3x year
FluoroType XDR	Validation Verification EQA	25 Specimens 12 Specimens 4 Specimens / 3x year
TB NGS & WGS (Pilot)	EQA Verification	4 Specimens / 3x year 8 Specimens

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SMARTSPOT QUALITY

HIV Quality Controls

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SmartSpot Quality offers a range of Quality Control Panels for HIV diagnostics:

ISO/IEC 17043:2010 Accredited

HIV Viral Load specimens: Modified human plasma specimens. Each specimen is blinded and classified as either **HIV Negative** or **HIV positive** of a known Viral Load.
HIV Qual specimens: Modified whole blood specimens or Dried Blood Spots (**DBS**). Each Specimen is blinded and classified as either **HIV Negative** or **HIV Positive**.
All specimens have been inactivated, are considered **non-infectious** modified human biological material and are categorised as "Exempt Human Specimens" according to IATA regulations.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for 4 weeks.
- In-depth support to laboratories via video conferencing, providing technical guidance and general operational advice.
- Online Quality Assessment Tool provided for submitting results and reviewing performance.
- Group Management Reports with analytics and insights for managers of institutions.

Validation: A single occasion exercise designed to test Precision and Accuracy of a new assay.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Special feature of the HIV Viral Load and Qual Programs:

SmartSpot Quality provides the **first non-infectious liquid** HIV EQA and Verification Control Program that is **stable at ambient temperature**. Currently controls are stable at room temperature for 4 weeks and a **12-month shelf-stable control** is under development.

Assay	QC Panel	Panel Constituents
Xpert HIV-1 Viral Load & Qual **Xpert HIV Viral Load XC & Qual XC**	Validation (Precision Study) Validation (Accuracy Study) Verification EQA	24 Specimens 10 Specimens 12 Specimens 4 Specimens / 3x year
Abbott m-Pima HIV Viral Load & Detect	Validation (Precision Study) Validation (Accuracy Study) Verification EQA	24 Specimens 10 Specimens 6 Specimens 4 Specimens / 3x year
Molecular* HIV Viral Load & Qualitative for: Roche Cobas, Roche CAP/CTM, Biomerieux, Abbott m2000 & Abbott Alinity, Hologic Panther, Biocentric etc*.	Validation (Precision & Accuracy Verification EQA	42 Specimens 12 Specimens 4 Specimens / 3x year

Note: *SmartSpot's Molecular controls have been validated on a wide variety of assays, for compatibility on additional assays, please enquire at* ***info@SmartSpotQ.com***.

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SMARTSPOT QUALITY

Viral Hepatitis Quality Controls

Scan for Catalogue

SmartSpot Quality offers a range of Quality Control Panels for Viral Hepatitis diagnostics:

ISO/IEC 17043:2010 Accredited

HBV Viral Load specimens: modified human plasma specimens. Each specimen is blinded and classified as either **HBV Negative** or **HBV positive** of a known Viral Load.

HCV Viral Load Plasma specimens: modified human plasma specimens. Each specimen is blinded and classified as either **HCV Negative** or **HCV positive** of a known Viral Load.

HCV Viral Load Whole Blood specimens: modified human whole blood specimens. Each specimen is blinded and classified as either **HCV Negative** or **HCV positive** of a known Viral Load.

All specimens have been inactivated, are considered **non-infectious** modified human biological material and are categorised as "Exempt Human Specimens" according to IATA regulations.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for 4 weeks (HBV Plasma) and 10 weeks (HCV Plasma and HCV Whole Blood)
- In-depth support to laboratories via video conferencing, providing technical guidance and general operational advice.
- Online Quality Assessment Tool provided for submitting results and reviewing performance.
- Group Management Reports with analytics and insights for managers of institutions.

Validation: A single occasion exercise designed to test Precision and Accuracy of a new assay.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Special feature of the Viral Hepatitis Programs:

HBV Plasma Controls are **stable at ambient temperatures for 4 weeks** and Whole Blood HCV Controls and HCV plasma controls are **stable for 10 weeks at ambient temperature**.

Stability of Plasma Specimens can be **extended** via storage at -20˚C (up to 6 months) or -80˚C (up to 12 months)
Stability of Whole Blood Specimens can be **extended** via storage at -20˚C (up to 4 months)

Assay	QC Panel	Panel Constituents
Molecular* HBV Viral Load	Validation (Precision Study)	24 Specimens
	Validation (Accuracy Study)	10 Specimens
	Verification	12 Specimens
	EQA	4 Specimens / 3x year
Molecular* HCV Viral load Molecular* HCV Viral Load Fingerstick	Validation (Precision Study)	24 Specimens
	Validation (Accuracy Study)	10 Specimens
	Verification	12 Specimens
	EQA	4 Specimens / 3x year

Note:* *SmartSpot's Molecular controls are initially validated for use on GeneXpert and are then validated on other platforms as customers show interest, Please enquire at **info@SmartSpotQ.com to confirm compatibility for alternative platforms.*

SMARTSPOT QUALITY

SARS-CoV-2 / Flu / RSV Quality Controls

Scan for Catalogue

SmartSpot Quality offers a range of Quality Control Panels for SARS-CoV-2, Flu and RSV diagnostics:

ISO/IEC 17043:2010 Accredited

Each DCS contains either one or more of the following targets **SARS-CoV-2, Flu A, Flu B, RSV A, RSV B and/or Negative** material – all of which are **inherently non-infectious**, inactivated, quantified and intact.
The SARS-CoV-2 positive DCS contain different combinations of the Targets in **N, E, S, Orf1a/b**, and **RdRP** regions enabling robust testing within the EQA Program.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for up to 18 months reducing shipping cost 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 results and reviewing performance.
- Group Management Reports with analytics and insights for managers of institutions.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Pre-Rollout Verification: A single occasion exercise designed to verify software, instrument and user training prior to commissioning the use of a new assay.

Special feature of the SARS-COV-2 / Flu / RSV Programs:

SmartSpot's Molecular SARS-CoV-2 / Flu / RSV controls are validated for use on GeneXpert. The SARS-CoV-2 controls are also validated on 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

Assay	QC Panel	Panel Constituents
Xpert Xpress SARS-CoV-2	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year
Molecular* SARS-CoV-2	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year
Molecular* SARS-CoV-2 / Flu / RSV	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year

Note:* *SmartSpot's Molecular controls have been validated on a wide variety of assays, for compatibility on additional assays, please enquire at **info@SmartSpotQ.com.*

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SMARTSPOT QUALITY

MRSA Quality Controls

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SmartSpot Quality offers a range of Quality Control Panels for MRSA diagnostics:

ISO/IEC 17043:2010 Accredited

Each control contains either one or more of the following targets **Methicillin-susceptible Staphylococcus aureus, Methicillin-resistant Staphylococcus aureus and/or Negative** material – all of which are **inherently non-infectious**, inactivated, quantified and intact.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for up to 18 months reducing shipping cost 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 results and reviewing performance.
- Group Management Reports with analytics and insights for managers of institutions.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Pre-Rollout Verification: A single occasion exercise designed to verify software, instrument and user training prior to commissioning the use of a new assay.

Special feature of the MRSA Programs:

SmartSpot's MRSA controls are inherently non-infectious, stable at room temperature and ships door-to-door within 2-8 days.

The MSSA and MRSA positive controls contain different combinations of the targets in **mec, spa** and **scc** regions enabling robust quality testing of MRSA mutations.

Assay	QC Panel	Panel Constituents
Xpert MRSA NxG **Xpert MRSA/SA Blood Culture** **Xpert MRSA Nasal Complete** **Xpert MRSA/SA SSTI**	Pre-rollout Verification	12 Specimens
	Verification	4 Specimens
	EQA	4 Specimens / 3x year
Molecular* MRSA/SA	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year

SmartSpot's Molecular controls are initially validated for use on GeneXpert and are then validated on other platforms as customers show interest, Please enquire at **info@SmartSpotQ.com to confirm compatibility for alternative platforms.*

SMARTSPOT QUALITY

HPV Quality Controls

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SmartSpot Quality offers a range of Quality Control Panels for HPV diagnostics:

ISO/IEC 17043:2010 Accredited

Each DCS contains either one or more of the following subtypes of HPV, **HPV 16, HPV 18, HPV 45 and/or HPV Negative** material – all of which are **inherently non-infectious**, inactivated, quantified and intact.

The different combinations of subtype targets in the HPV Positive DCS enable robust testing within the EQA Program.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for up to 12 months reducing shipping cost 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 results and reviewing performance.
- Group Management Reports with analytics and insights for managers of institutions.

Validation: A single occasion exercise designed to test Reproducibility of a new assay across HPV subtypes 16, 18 & 45.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Special feature of the HPV Programs:

SmartSpot's HPV controls are stable at room temperature, non-infectious and validated for use with both PreservCyt and Saline.

Compatible with GeneXpert. For compatibility on alternative instruments, please contact us for more information on **info@SmartSpotQ.com**

Assay	QC Panel	Panel Constituents
Xpert HPV	Validation Verification EQA	20 Specimens 12 Specimens 4 Specimens / 3x year
Molecular HPV	Validation Verification EQA	20 Specimens 12 Specimens 4 Specimens / 3x year

SMARTSPOT QUALITY

STI Quality Controls

Scan for Catalogue

ISO/IEC 17043:2010 Accredited

SmartSpot Quality offers a range of Quality Control Panels for STI diagnostics:

Each control contains either one or more targets for the following Sexually Transmitted Infections (STI's): **Chlamydia Trachomatis, Neisseria Gonorrhoea, Syphilis and/or Negative** material – all of which are **non-infectious**, inactivated, quantified and intact.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for up to 4 weeks.
- In-depth support to laboratories via video conferencing, providing technical guidance and general operational advice.
- Online Quality Assessment Tool provided for submitting results and reviewing performance.
- Group Management Reports with analytics and insights for managers of institutions.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Pre-Rollout Verification: A single occasion exercise designed to verify software, instrument and user training prior to commissioning the use of a new assay.

Special feature of the STI Programs:

SmartSpot's CT/NG controls are non-infectious, stable at room temperature and ships door-to-door within 2-8 days.

The STI Quality controls can be used independent from one another or tested together in groupings.

Assay	QC Panel	Panel Constituents
Xpert CT/NG	Pre-rollout Verification	12 Specimens
	Verification	4 Specimens
	EQA	4 Specimens / 3x year
Molecular Syphilis	Pre-rollout Verification	12 Specimens
	Verification	4 Specimens
	EQA	4 Specimens / 3x year
Molecular* CT/NG	Pre-rollout Verification	12 Specimens
	Verification	4 Specimens
	EQA	4 Specimens / 3x year

SmartSpot's Molecular controls are initially validated for use on GeneXpert and are then validated on other platforms as customers show interest, Please enquire at **info@SmartSpotQ.com to confirm compatibility for alternative platforms.*

SMARTSPOT QUALITY

C. difficile Quality Controls

Scan for Catalogue

SmartSpot Quality offers a range of Quality Control Panels for C. difficile diagnostics:

ISO/IEC 17043:2010 Accredited

Each control contains either one or more of the following targets: **Toxin A, Toxin B, Binary Toxin and/or Negative** material – all of which are **non-infectious**, inactivated, quantified and intact.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for up to 18 months.
- In-depth support to laboratories via video conferencing, providing technical guidance and general operational advice.
- Online Quality Assessment Tool provided for submitting results and reviewing performance.
- Group Management Reports with analytics and insights for managers of institutions.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Pre-Rollout Verification: A single occasion exercise designed to verify software, instrument and user training prior to commissioning the use of a new assay.

Special feature of the C. difficile Programs:

SmartSpot's C. difficile controls are non-infectious, stable at room temperature and ships door-to-door within 2-8 days.

The Toxigenic C. difficile and Binary Toxin positive controls contain different combinations of the targets in **cdtA, tcdA, tcdB and tcdC** regions enabling robust quality testing of C. difficile mutations.

Assay	QC Panel	Panel Constituents
Xpert C. difficile	Pre-rollout Verification	12 Specimens
	Verification	4 Specimens
	EQA	4 Specimens / 3x year
Molecular* C. difficile	Pre-rollout Verification	12 Specimens
	Verification	4 Specimens
	EQA	4 Specimens / 3x year

SmartSpot's Molecular controls are initially validated for use on GeneXpert and are then validated on other platforms as customers show interest, Please enquire at **info@SmartSpotQ.com to confirm compatibility for alternative platforms.*

SMARTSPOT QUALITY

Programs in Pilot & Development Phase

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SmartSpot Quality offers a range of Quality Control Panels for molecular diagnostics:

PILOT/ IN DEVELOPMENT

SmartSpot is recruiting participants for the Pilots listed below. Should you be interested in participating in 2024 / 2025, please contact Orders@SmartSpotQ.com

The Quality Control Programs listed below are new and are not yet ISO/IEC 17043:2010 accredited.

PILOT: Internally validated by SmartSpot and ***available to participants***.

IN DEVELOPMENT: Controls are currently being developed and are not yet available to participants.

Verification: A single occasion exercise used upon Installation, Relocation, Post-Calibration or Post Module replacement to verify that an instrument is fit for purpose.

EQA: Assessments run 3x per annum to identify Pre- and Post-Analytical errors such as: Sample ID switching, Cross-Contamination, Sample preparation Errors & anomalies in Probe detection.

Pre-Rollout Verification: A single occasion exercise designed to verify software, instrument and user training prior to commissioning the use of a new assay.

WHY OUR PROGRAMS ARE INDUSTRY LEADING

- Controls are stable at ambient temperatures for between 4 weeks and up to 36 months.
- In-depth support to laboratories via video conferencing, providing technical guidance and general operational advice.
- Online Quality Assessment Tool provided for submitting results and reviewing performance.
- Group Management Reports with analytics and insights for managers of institutions.

Assay	QC Panel	Panel Constituents
Molecular* NGS/WGS (Pilot)	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year
Molecular* TV/MG (Pilot)	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year
Molecular* Carba R (Pilot)	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year
Molecular* CD4 (In Development)	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year
Molecular* Breast Cancer STRAT4 (In Development) **Bladder Cancer Detection**	Pre-rollout Verification Verification EQA	12 Specimens 4 Specimens 4 Specimens / 3x year

Note:* SmartSpot's Molecular controls are initially validated for use on GeneXpert and are then validated on other platforms as customers show interest, Please enquire at ***info@SmartSpotQ.com* to confirm compatibility for alternative platforms.*