

Accessing Sequence Screening Conformity Assessments

MITRE, IBBIS, and SecureDNA

A guide for IGSC members meeting HSP v3.1 §7.2.6

Why This Matters

HSP v3.1 — Requirement 2.6

"IGSC companies regularly evaluate the efficacy of their automated sequence screening for identifying Sequences of Concern using a Sequence of Concern test set supplied by an IGSC-recognized source of Sequence of Concern standards (See Section 9.3). Evaluations are performed at least once every 12 months."

Per **HSP §9.3**, the IGSC currently recognizes two sources of Sequence of Concern (SoC) standards:

- **NIST** (National Institute of Standards and Technology) — accessible via **IBBIS**, **SecureDNA**, or **MITRE**
- **SBRC** (Sequence Biosecurity Risk Consortium) — available directly, and IGSC members have access as an SBRC consortium member

This guide summarizes the three current pathways for obtaining a NIST-based evaluation and explains how they differ. **All three use the same underlying NIST test-set methodology and the same passing thresholds**, so the choice between them is mostly about process, cadence, and who administers the evaluation.

The Common Pass/Fail Standard

All three pathways score submissions against the same two thresholds, calculated on the graded portion of the test set:

Metric	Formula	Passing Threshold
Sensitivity (Recall)	$TP / (TP + FN)$	$\geq 95\%$
Accuracy	$(TP + TN) / \text{Total graded}$	$\geq 75\%$

A result is a **pass** only if **both** thresholds are met. Across all three providers, a passing result is explicitly **not** a certification, accreditation, validation, or endorsement — it documents a single blinded performance check, valid toward the HSP's annual evaluation requirement.

OPTION 1 IBBIS Evaluation Portal

Administered by: International Biosecurity and Biosafety Initiative for Science (IBBIS)

How it works

1. Sign up on the [IBBIS evaluation portal](#) with your organization's details and confirm your email.
2. Log in to reach your dashboard, which offers two tracks: the **NIST Study Guide** — a labeled practice dataset (~50 sequences) — and the **NIST Baseline Evaluation** — the official current month's dataset (~1,000 sequences) used for the graded assessment.
3. Request the current month's dataset from the dashboard (or email rassin@ibbis.bio if you don't have the latest one).
4. Run the provided FASTA — each entry includes a **UUID** and **Sequence** — through your screening tool.
5. Upload results as **CSV or TSV** on the “Upload and Evaluate Dataset Results” page, including a boolean **Flag** column (1 = flagged, 0 = not flagged), and select the correct month's dataset.
6. The portal scores your submission and returns **Pass/Fail** based on the thresholds above.

Key details

- **Monthly rotation** — datasets are rotated monthly; only the most recent dataset counts for an official (graded) result.
- Older datasets are available on request for practice/trial runs.
- **Passing results expire after one month** in the portal, so time your official run to align with when you need documentation.
- If you pass, you can download a **PDF** from the upload page or dashboard to demonstrate compliance to the IGSC.
- If you fail, results remain visible to you for troubleshooting.
- SBRC datasets were expected to become available on the portal in Q3 2026, cycled quarterly.
- **Contact:** Rassin Lababidi (rassin@ibbis.bio)

OPTION 2 MITRE Sequence Screening Proficiency Testing

Administered by: The MITRE Corporation

How it works

1. MITRE provides your organization with a **current blinded NIST or SBRC test set**.
2. Your team screens every sequence using your **normal production process** (not a special-case workflow).
3. You return **Positive/Negative (P/N) decisions** in the response spreadsheet MITRE provides.
4. MITRE — which keeps the test data separate from the answer key — scores your submission against the hidden key and reports the outcome back to you.

Key details

- Test sets are drawn from **NIST and SBRC**, satisfying HSP §9.3's recognized-source requirement either way.
- Cadence: at least once every 12 months, consistent with HSP §7.2.6.
- Results reflect **one submitted run** against a blinded test set — they do not certify, accredit, validate, or endorse your full order-screening process, systems, or regulatory compliance.
- MITRE frames this as a **public-interest service**: a neutral, standards-based benchmark to help the synthesis community track performance, document annual completion, and prioritize follow-up improvements.
- **Contact:** John Dileo (jdileo@mitre.org); see also mitre.org/bio

OPTION 3 SecureDNA Data Test Set

Administered by: SecureDNA Foundation (Basel, Switzerland), in a joint effort with NIST

How it works

1. Submit a request through SecureDNA's [Data Test Set request form](#) with organizational registration and acceptance of applicable terms.
2. SecureDNA emails a secure download link containing a FASTA of **1,000 blinded sequences**, a FASTA of **~50 sample sequences** to verify ingest/reporting, a TSV of expected results for the samples, and a results-reporting template.
3. Screen the sequences using your **standard procedure** and return results in the provided template.
4. SecureDNA scores the graded subset (a hidden **~400 of the 1,000 sequences**) against the same Accuracy $\geq 75\%$ / Sensitivity $\geq 95\%$ thresholds.

Key details

- **Turnaround:** results are expected back within one week of receiving the link and template.
- One official submission per dataset per organization, per month.
- **Confidentiality:** evaluation datasets and detailed results may not be shared outside your organization, except for the explicit PASS notice you may choose to share; NIST receives only anonymized, aggregated statistics.
- **Validity window:** during SecureDNA's alpha phase, PASS notices expire after 30 days; during the beta phase they are valid for 1 year — worth confirming current phase status when you request access.
- Open to commercial and academic synthesis providers, benchtop platform vendors, tool developers, and other stakeholders with a legitimate evaluation need.
- **Contact:** contact@securedna.org

Side-by-Side Comparison

	IBBIS	MITRE	SecuredNA
Test set source(s)	NIST (SBRC planned Q3 2026)	NIST or SBRC	NIST
Access model	Self-service portal account	Direct outreach to MITRE contact	Online request form + registration
Dataset size	~1,000 sequences (monthly)	Blinded set provided by MITRE	1,000 sequences (~400 graded), monthly
Practice / sample set	Yes — NIST Study Guide (~50 seqs)	Not specified	Yes — ~50 sample sequences w/ expected results
Submission format	CSV/TSV with boolean Flag column	Spreadsheet with P/N decisions	Provided results-reporting template
Passing thresholds	Accuracy ≥ 75%, Sensitivity ≥ 95%	Accuracy ≥ 75%, Sensitivity ≥ 95%	Accuracy ≥ 75%, Sensitivity ≥ 95%
Result validity	Expires after 1 month in portal	Not specified	30 days (alpha) or 1 year (beta)
Proof of pass	Downloadable PDF	Reported outcome from MITRE	PASS notice (opt-in shareable)
Point of contact	rassin@ibbis.bio	jdileo@mitre.org	contact@securedna.org

Practical Notes for IGSC Members

- ✓ **Any one of the three satisfies HSP §9.3**, since all draw on NIST (and, for MITRE, optionally SBRC) test sets. You do not need to use more than one pathway to meet the annual requirement — pick whichever fits your workflow and record-keeping preferences.
- ✓ **Watch the 12-month clock (§7.2.6)** alongside each provider's own result-validity window — a pass that expires in 30 days (SecuredNA alpha) or 1 month (IBBIS) may need to be re-run closer to when you need to show documentation, even though the HSP itself only requires evaluation at least annually.
- ✓ **Use the practice/sample sets first.** Both IBBIS and SecuredNA offer a smaller labeled set to confirm your pipeline (data ingest, reporting format) works correctly before you spend your one official monthly submission.
Note: NIST also provides a public reference data set at data.nist.gov/od/id/mds2-3787, which members can also use to familiarize themselves with the test-set format.
- ✓ **Keep your Pass documentation.** Retain the PDF (IBBIS), reported outcome (MITRE), or PASS notice (SecuredNA) as your evidence of completing the HSP §7.2.6 evaluation for that year.
- ✓ **Confidentiality applies.** SecuredNA explicitly restricts sharing of test sequences and detailed results outside your organization; treat test materials from IBBIS and MITRE with the same discretion absent guidance otherwise.
- ✓ **Send your documentation to IGSC.** Send your passing documentation (PDF, reported outcome, or PASS notice) to the IGSC Program Manager at sroy@genesynthesisconsortium.org, and your member file and web presence will be updated accordingly.