510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K254121

B Applicant

DNA Genotek, Inc.

C Proprietary and Established Names

Colli-Pee•Dx Urine Collection Kit

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SIH	Class II	21 CFR 866.2920 - Device for home collection and transportation of clinical specimens by lay users for infectious disease testing	Microbiology

II Submission/Device Overview:

A Error! Bookmark not defined. Purpose for Submission:

To determine substantial equivalence for the Colli-Pee•Dx Urine Collection Kit, a device for the self-collection of first-void urine for the purpose of collecting and transporting specimens for use in an FDA cleared sexually transmitted infection (STI) molecular assay with which the device has been validated.

B Measurand

Not applicable.

C Type of Test

First-void urine collection for testing with an FDA cleared STI molecular assay. Performance of this device has only been validated with the cobas CT/NG (K173887) and cobas TV/MG (K190433).

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Colli-Pee•Dx Urine Collection Kit is a device for the self-collection of first-void urine for the purpose of collecting and transporting specimens for use in an FDA cleared STI molecular assay with which the device has been validated. Colli-Pee•Dx Urine Collection Kit can be used at-home or in any private setting.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

Performance characteristics of this device have only been validated with the cobas CT/NG (Kl73887) and cobas TV/MG (K190433).

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:
The Colli-Pee•Dx Urine Collection Kit enables the standardized, volumetric collection of first-void urine and sample stabilization. Samples collected at home or in any private setting are mailed to a laboratory for testing. In the laboratory, the urine sample is tested using an FDA cleared STI molecular assay with which the device has been validated. The Colli-Pee•Dx Urine Collection Kit has been validated with the cobas CT/NG and cobas TV/MG. The Colli-Pee•Dx Urine Collection Kit is single use and must be prescribed by a medical provider.

Device Components
The Colli-Pee•Dx Urine Collection Kit consists of:
1) Colli-Pee •Dx device
   - Funnel
   - Specimen tube and cap with 0.67 mL of stabilizing liquid
   - Instructions for Use
2) Return instructions card
3) Bubble bag
4) Bio-specimen bag
5) Mailer box
6) Mailing materials (supplied by the test provider)

Figure. Representative image of the Colli-Pee•Dx Urine Collection Kit for at-home collection

B Principle of Operation:

The user follows the provided instructions to collect first-void urine using the Colli-Pee•Dx Urine Collection Kit, the user locates the Colli-Pee•Dx device in the mailer box, opens the pouch, attaches the funnel to the tube and positions it for collection. The device automatically captures a pre-defined fixed volume of first-void urine, while residual urine passes through the outlet and is discharged into the toilet. After urination, the funnel is removed and discarded, the tube is sealed with a cap and inverted manually by the user 10 times to mix the sample with stabilizing liquid. The collected sample is mailed back to the laboratory using the mailer box.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Teal Wand

B Predicate 510(k) Number(s):

DEN240045

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251440	DEN240045
Device Trade Name	Colli-Pee•Dx Urine Collection Kit	Teal Wand

General Device Characteristic Similarities		
Intended Use/Indications For Use	The Colli-Pee•Dx Urine Collection Kit is a device for the self-collection of first-void urine for the purpose of collecting and transporting specimens for use in an FDA cleared STI molecular assay with which the device has been validated. Colli-Pee•Dx Urine Collection Kit can be used at-home or in any private setting.	The Teal Wand is a device for the self-collection of vaginal specimens for the purpose of collecting and transporting specimens for use in an FDA approved HPV molecular assay with which the collection device has been validated. The Teal Wand can be used at-home or in any private setting. Specimens can be collected, stored, and shipped dry in an empty vial.
Conditions for Use	At-home or any private setting by prescription only	Same
General Device Characteristic Differences		
Specimen Type	Urine	Vaginal swab
Principle of Operation	Sample collection by urinating through a funnel connected to a collection tube with stabilizing liquid	Sample collection by inserting device into vaginal opening and placing collection sponge into empty vial
Specimen Transport	Transported in a collection tube with stabilizing liquid	Transported dry in an empty vial
Validated Assay(s)	cobas CT/NG and cobas TV/MG	cobas HPV

VI Standards/Guidance Documents Referenced:

21 CFR 866.2920 Special controls

ISO 10993-1: 2020 5th Edition – Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process.

ISO 14971: 2019 3rd Edition – Medical devices – Application of risk management to medical devices.

ASTM D4169:22 – Standard Practice for Performance Testing of Shipping Containers and Systems.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision:
   A precision study was conducted using three lots of the Colli-Pee•Dx Urine Collection Kit. Negative male and female urine matrix co-spiked with *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) was added to Colli-Pee•Dx devices. Samples were spiked at concentrations representative of low- and high-positive samples. Analyte-negative male and female urine samples were also included. All samples tested using the cobas CT/NG assay produced the expected results at baseline and following test conditions.

2. Linearity:
   Not applicable.

3. Analytical Specificity/Interference:

   Interference Substances Study
   A study was performed to evaluate whether relevant endogenous and exogenous substances, including substances commonly used by lay users at home or in any private settings may interfere with the detection of CT, NG, *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) using Colli-Pee•Dx collected urine samples. Both positive and negative urine samples were tested with and without the potential interfering substances. The positive samples were prepared using male and female negative urine matrix co-spiked with low concentrations of CT and NG or TV and MG. Substances tested are described in Tables 1 and 2. The indicated concentrations represent the tested concentration of a substance, when assessed with the cobas CT/NG and cobas TV/MG assays, that did not result in interference. For additional interfering substance study data, refer to Kl73887 and K190433.

Table 1. Interfering Substances Study Results with cobas CT/NG assay.

Test substance	Concentration without Interference
Low pH	4
High pH	9
Protein	0.5% (w/v)*
Blood	1% (w/v)*
Mucus	0.5% (w/v)
Summer's Eve Deodorant	0.25% (w/v)
Vagisil Deodorant	0.25% (w/v)
Vagisil Feminine Powder	0.25% (w/v)
Monistat Vaginal Cream	0.25% (w/v)
Vagisil Vaginal Cream	0.25% (w/v)
RepHresh Vaginal Gel	0.25% (w/v)
Gynalac Vaginal Gel	0.25% (w/v)

CeraVe Lotion	0.1% (w/v)
Purell Hand Sanitizer	0.1% (w/v)
Zytec Hand Sanitizer	0.1% (w/v)
Soft Soap Hand Soap	0.001% (w/v)
Dial Hand Soap	0.001% (w/v)
Banana Boat Sunscreen	0.1% (w/v)
Coppertone Sunscreen	0.1% (w/v)
Water	10% (w/v)

*Interference was observed at concentrations above this level.

Table 2. Interfering Substances Study Results with cobas TV/MG assay.

Test substance	Concentration without Interference
Low pH	4
High pH	9
Protein	0.5% (w/v)
Blood	5% (w/v)
Mucus	0.5% (w/v)
Summer's Eve Deodorant	0.1% (w/v)
Vagisil Deodorant	0.1% (w/v)
Vagisil Feminine Powder	0.1% (w/v)
Monistat Vaginal Cream	0.1% (w/v)
Gynalac Vaginal Gel	0.1% (w/v)
CeraVe Lotion	0.1% (w/v)
Purell Hand Sanitizer	0.1% (w/v)
Zytec Hand Sanitizer	0.1% (w/v)
Soft Soap Hand Soap	0.001% (w/v)
Dial Hand Soap	0.001% (w/v)
Banana Boat Sunscreen	0.1% (w/v)
Coppertone Sunscreen	0.1% (w/v)
Water	10% (w/v)

4. Detection Limit:

The Limit of Detection (LoD) for CT, NG, TV and MG was determined using representative target microorganisms in pooled negative male and female urine, collected in Colli-Pee•Dx Urine Collection Kit and then tested with the cobas CT/NG and cobas TV/MG assays, respectively. For the preliminary LoD, five independent replicates were co-spiked with either CT/NG or TV/MG across a range of five concentrations. The LoD was confirmed by testing 20 replicates at the preliminary LoD for each microorganism to determine the concentration that gave positive test results in ≥95% of the samples (at least 19/20 replicates testing positive for each strain). Results are shown in Table 3.

Table 3. LoD of CT, NG, TV and MG in Negative Clinical Urine Matrix

Colli-Pee	CT	NG	TV	MG
Male	10 IFU/mL	0.25 CFU/mL	0.5 cells/mL	3 cp/mL
Female	2 IFU/mL	0.25 CFU/mL	0.5 cells/mL	3 cp/mL

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Shelf-life Stability
The Colli-Pee•Dx Urine Collection Kits underwent stability testing following exposure to real-time aging conditions to support a shelf-life of 12 months. For real-time aging, the Colli-Pee•Dx devices were stored at temperatures flanking the labeled storage temperature of 15°C to 30°C/59°F to 86°F. At each study time point, functional (cobas CT/NG and cobas TV/MG assays), chemical and physical (pH, Refractive Index, chemistry visual inspection, evaporation and visual inspection of plastics/labels/pouch) endpoints were evaluated in three (3) lots of devices at baseline and following exposure to the various test conditions. For functional performance testing, male and female negative urine matrix co-spiked CT and NG or TV and MG at concentrations representative of low-positive samples and analyte-negative samples were added to the aged Colli-Pee•Dx devices and tested. A subset of devices containing co-spiked urine samples were subsequently stored at 32°C for 33 days to evaluate stability of the microorganisms in the aged devices. Study results showed that the Colli-Pee•Dx devices performed as expected, with the results supporting a shelf-life of 12 months.

Sample Stability
A sample stability study was conducted using replicates of analyte-negative male and female urine samples and positive samples (male and female negative urine matrix co-spiked with either CT and NG or TV and MG at concentrations representative of low-positive and/or high-positive samples). The study evaluated the Colli-Pee•Dx Urine Collection Kit performance for sample shipping and laboratory storage stability under the following test conditions:

- Simulated summer and winter transport profile cycling conditions (-10°C to 40°C/14°F to 104°F) representing extreme cold and hot temperatures for durations anticipated during a 130-hour (5-day) shipping period from the time of sample collection to receipt at the testing laboratory.
- Simulated summer and winter transport followed by 30 days of storage in the laboratory at temperatures (2°C to 30°C/36°F to 86°F)

At the study timepoints, both positive and negative sample in multiple replicates were tested with cobas CT/NG and/or cobas TV/MG assays. Expected results were obtained for all negative and positive samples at all conditions.

6. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Analytical equivalency of Collection Media and Collection Devices:

   The Colli-Pee•Dx Urine Collection Kit and the FDA cleared on-label urine collection kit, containing different collection media, were compared in this study. The samples were prepared by co-spiking negative male and female urine, collected using the two collection kits, with either CT/NG or TV/MG at, above and below the LoD and were tested on cobas

CT/NG and cobas TV/MG assays. The study results demonstrated that the Colli-Pee•Dx Urine Collection Kit is analytically equivalent to the FDA cleared on-label urine collection kit.

Table 4. Summary of % Positivity for CT/NG or TV/MG Co-Spiked Male First-Void Urine in the Colli-Pee•Dx Urine Collection Kit and the FDA Cleared On-Label Urine Collection Kit Tested Using the cobas CT/NG and cobas TV/MG assays.

Analyte	Concentration	Male			
		Colli-Pee	FDA-Cleared	Colli-Pee	FDA-Cleared
		% Agreement		Mean (SD)	
CT	4 IFU/mL	60%	60%	33.91 (0.08)	36.07 (0.32)
	10 IFU/mL	100%	100%	33.35 (0.29)	35.55 (0.71)
	20 IFU/mL	100%	100%	32.44 (0.16)	33.93 (0.44)
	40 IFU/mL	100%	100%	31.63 (0.23)	33.19 (0.38)
	120 IFU/mL	100%	100%	30.00 (0.27)	31.68 (0.27)
NG	0.1 CFU/mL	80%	80%	36.00 (0.60)	38.17 (1.13)
	0.25 CFU/mL	100%	88%	35.15 (0.97)	37.83 (1.86)
	0.5 CFU/mL	100%	100%	34.47 (0.57)	36.02 (0.61)
	1 CFU/mL	100%	100%	32.96 (0.20)	34.88 (0.62)
	3 CFU/mL	100%	100%	31.47 (0.37)	33.17 (0.22)
TV	0.5 cells/mL	100%	100%	32.54 (1.43)	34.10 (0.87)
	0.8 cells/mL	100%	100%	31.55 (0.91)	33.10 (1.49)
	1.1 cells/mL	100%	100%	31.44 (0.86)	32.81 (1.27)
	1.4 cells/mL	100%	100%	30.80 (0.33)	33.07 (0.30)
	1.7 cells/mL	100%	100%	30.56 (0.34)	32.44 (0.55)
MG	3 cp/mL	100%	92%	34.67 (0.79)	36.03 (1.11)
	3.5 cp/mL	100%	80%	34.05 (1.61)	36.77 (1.36)
	4 cp/mL	100%	100%	35.01 (1.15)	38.10 (1.68)
	4.5 cp/mL	100%	80%	34.60 (1.08)	37.78 (0.88)
	5 cp/mL	100%	100%	34.71 (0.24)	36.81 (1.33)

Table 5. Summary of % Positivity calls for CT/NG or TV/MG co-spiked Female first-void urine in the Colli-Pee•Dx Urine Collection Kit and the FDA cleared on-label urine collection kit on the cobas CT/NG and cobas TV/MG assays

Analyte	Concentration	Female			
		Colli-Pee	FDA-Cleared	Colli-Pee	FDA-Cleared
		% Agreement		Mean +/- SD	
CT	1 IFU/mL	60%	80%	36.07 (1.44)	37.73 (1.84)
	2 IFU/mL	100%	96%	36.47 (0.76)	37.67 (0.95)
	4 IFU/mL	100%	100%	34.84 (0.55)	36.51 (0.73)
	10 IFU/mL	100%	100%	33.36 (0.48)	34.71 (0.55)
	20 IFU/mL	100%	100%	32.31 (0.08)	33.59 (0.12)
NG	0.1 CFU/mL	40%	60%	35.57 (0.41)	37.09 (0.91)
	0.25 CFU/mL	100%	95%	35.53 (1.08)	37.23 (1.08)
	0.5 CFU/mL	100%	100%	33.60 (0.23)	35.77 (1.25)
	1 CFU/mL	100%	100%	32.82 (0.52)	34.78 (0.48)
	3 CFU/mL	100%	100%	31.55 (0.14)	33.38 (0.23)
TV	0.5 cells/mL	100%	100%	32.53 (1.43)	33.97 (0.77)
	0.8 cells/mL	100%	100%	31.91 (0.95)	33.18 (0.83)

	1.1 cells/mL	100%	100%	31.50 (0.59)	32.79 (0.76)
	1.4 cells/mL	100%	100%	31.44 (0.52)	32.46 (0.63)
	1.7 cells/mL	100%	100%	30.92 (0.61)	32.76 (0.52)
MG	3 cp/mL	96%	96%	34.29 (1.15)	35.82 (0.79)
	3.5 cp/mL	100%	100%	34.00 (0.65)	35.04 (0.91)
	4 cp/mL	100%	80%	33.95 (0.92)	34.56 (0.64)
	4.5 cp/mL	100%	100%	33.65 (1.59)	34.49 (1.74)
	5 cp/mL	100%	100%	35.05 (0.82)	35.85 (1.24)

C Clinical Studies:

The clinical performance of the Colli-Pee•Dx Urine Collection Kit is supported by the following datasets:

The clinical performance for male and female urine was established in K173887 and K190433 and data were leveraged based on the established equivalence.

A separate prospective clinical study was conducted, enrolling female participants, to support the performance of the Colli-Pee•Dx Urine Collection Kit for use with cobas CT/NG and cobas TV/MG assays. Female participants (n=1357) were enrolled at 11 enrollment sites across the US between November 3, 2025, and April 9, 2026. Each participant self-collected three specimens in simulated home environment following respective instructions for use: a urine specimen collected using the FDA-cleared on-label urine collection kit, a urine specimen collected using the Colli-Pee•Dx Urine Collection Kit, and a vaginal swab specimen collected using the FDA-cleared on-label kit. All specimens were tested per cobas CT/NG and cobas TV/MG assay instructions. The Colli-Pee•Dx Urine Collection Kit performance was calculated by comparing each urine collection device result to the paired vaginal swab result to determine the ratios (Colli-Pee•Dx Urine Collection Kit: on-label urine collection kit) of Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA). The performance for each analyte is summarized in Table 6.

Table 6. Ratios of Agreement with the Vaginal Swab Specimens for the Colli-Pee•Dx Urine Collection Kit as Compared to the FDA Cleared On-Label Urine Collection Kit.

Target Analyte	Ratio of Positive Percent Agreement (PPA)	Ratio of Negative Percent Agreement (NPA)
CT	1.027 (95% CI: 0.973, 1.081)	1.000 (95% CI: 0.998, 1.002)
NG	0.947 (95% CI: 0.847, 1.048)	1.000 (95% CI: N/A*)
TV	1.046 (95% CI: 0.993, 1.100)	0.998 (95% CI: 0.992, 1.004)
MG	1.103 (95% CI: 0.980, 1.226)	1.004 (95% CI: 0.998, 1.010)

*95% CI by normal approximation is not available.

D Expected Values/Reference Range:

Not Applicable.

E Other Supportive Instrument Performance Characteristics Data:

Usability and User Comprehension

Device usability and user comprehension was assessed to demonstrate the safety and effectiveness of the Colli-Pee•Dx Urine Collection Kit for the at-home self-collection of first-void urine. The study was designed to simulate a workflow of the at-home self-collection of urine for testing on the cobas CT/NG and cobas TV/MG assays. Users were mailed the Colli-Pee•Dx Urine Collection Kit, instructed to self-collect a urine specimen and mail the sample back to a testing laboratory. The study population of 219 naïve users included male and female participants ages 14 years and older, across different education levels and demographic groups representative of the U.S. general population. Usability study results demonstrated high user comprehension and ability to execute procedural steps across study participants.

Hazard Analysis and Mitigations

A comprehensive hazard analysis of the Colli-Pee•Dx Urine Collection Kit was conducted in accordance with ISO 14971:2019, to identify known and foreseeable hazards and hazardous situations and ensure that their risks are appropriately assessed and controlled when used under the conditions of intended use. Specific risks associated with human factors, sample and device handling, storage, and environmental factors were evaluated. Risk control measures have been implemented to reduce the risks.

Tests Evaluating Colli-Pee•Dx Urine Collection Kit Robustness

To demonstrate Colli-Pee•Dx Urine Collection Kit robustness, kits were challenged under the following conditions and low-positive and negative samples were tested with cobas CT/NG or cobas TV/MG assays:

- Urine collection volume variability
- Insufficient mixing of the specimen with stabilizing liquid

Across all testing conditions, expected results were obtained.

To demonstrate that Colli-Pee•Dx Urine Collection Kit can withstand shipping without affecting product integrity, the kits were challenged and tested in accordance with ASTM D4169 standard testing, and the packages and components within the kit were inspected for damage after challenge. After undergoing drop, compression, and vibration testing no damage was found, with the results demonstrating the mechanical robustness of the Colli-Pee•Dx Urine Collection Kit.

Frequently Asked Questions

A Frequently Asked Questions (FAQ) section has been included for lay users to provide educational information regarding the safety, benefit, and precautions of self-collection.

Biocompatibility

Biocompatibility risk assessment for the different housing components for the Colli-Pee•Dx Urine Collection Kit and chemical toxicity assessment evaluating the worst-case exposure of the chemicals in the stabilizing liquid was conducted and yielded acceptable results.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.