September 11, 2025

Immunalysis Corporation
Shubhajit Mitra
Senior Manager, Regulatory Affairs
829 Towne Center Drive
Pomona, California 91767

Re: K252520
Trade/Device Name: SEFRIA™ Hydrocodone Oral Fluid
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: August 8, 2025
Received: August 11, 2025

Dear Shubhajit Mitra:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH A. KOTAREK -S

Digitally signed by JOSEPH A. KOTAREK -S
Date: 2025.09.11 07:46:56 -04'00'

Joseph Kotarek
Branch Chief for Toxicology
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
k252520

Device Name
SEFRIA™ Hydrocodone Oral Fluid

Indications for Use *(Describe)*
The Immunalysis SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay is an enzyme immunoassay with a cutoff of 30 ng/mL in neat oral fluid collected by Quantisal™ or Quantisal™ II Oral Fluid Collection Device. The assay is intended for the qualitative and semi-quantitative analysis of hydrocodone in human oral fluid to be used with clinical analyzers. This assay is calibrated against hydrocodone.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The Immunalysis SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC-MS or LC-MS/MS are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are used.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with 21 CFR Section 807.92.

Submitter

510(k) Number:	K252520
Applicant Name:	Immunalysis Corporation 829 Towne Center Drive Pomona, CA 91767
FDA Establishment #:	2020952
Primary Correspondent:	Shubhajit Mitra Senior Manager, Regulatory Affairs
Primary Phone:	508-330-4796
Primary Email:	shubhajit.mitra@abbott.com
Alternate Correspondent:	Iris Saliba Director, Regulatory Affairs
Secondary Phone:	619-540-3931
Alternate Email:	iris.saliba@abbott.com
Date Prepared:	Sep 08, 2025

1. Device Information

Trade or Proprietary Names:	SEFRIA™ Hydrocodone Oral Fluid
Common Name:	Immunalysis SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay
Device Classification Name:	Enzyme Immunoassay, Opiates
Product Codes:	DJG
Regulatory Class:	Class II
Classification Regulation:	21 CFR 862.3650
Panel:	Toxicology (91)

2. Predicate Information

Company:	Immunalysis Corporation
Device:	SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay (K203564)

3. Device Description

The Immunalysis SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay is a homogenous enzyme immunoassay with a cutoff of 30 ng/mL in neat oral fluid. The assay is intended for use in laboratories with clinical chemistry analyzers for the qualitative and semi-quantitative analysis of hydrocodone in human oral fluid collected with Quantisal™ Oral Fluid Collection Device or Quantisal™ II Oral Fluid collection device.

4. Indication for Use

The Immunalysis SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay is an enzyme immunoassay with a cutoff of 30 ng/mL in neat oral fluid collected by Quantisal™ or Quantisal™ II Oral Fluid Collection Device. The assay is intended for the qualitative and semi-quantitative analysis of hydrocodone in human oral fluid to be used with clinical analyzers. This assay is calibrated against hydrocodone.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The Immunalysis SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography- Tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Professional judgment should be applied to any test result, particularly when preliminary positive results are used.

5. Comparison to Predicate Device

The subject device has the same design and functionality as the predicate device.

Table 1: Device Comparison

Device Characteristics	Predicate Device SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay (K203564)	Candidate device SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay
Similarities		
Assay Materials	Ready to use reagents: Antibody reagent, drug conjugate reagent	Same
Test Principle	Homogenous, competitive	Same
Measurement mode	Qualitative and semi-quantitative	Same
Cutoff Level	30 ng/mL in neat oral fluid	Same
Sample matrix	Oral fluid	Same
Reagent Storage	2 - 8°C until expiration date	Same
Instrumentation	Automated clinical chemistry analyzer	Same

Device Characteristics	Predicate Device SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay (K203564)	Candidate device SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay
Mass Spectrometry Confirmation	Required for preliminary positive results	Same
Associated oral fluid collection device	Quantisal™ or Quantisal™ II Oral Fluid Collection Device	Same
Differences		
Intended Use	Qualitative and semi-quantitative analysis of **oxycodone** in human oral fluid collected by Quantisal™ or Quantisal™ II Oral Fluid Collection Device	Qualitative and semi-quantitative analysis of **hydrocodone** in human oral fluid collected by Quantisal™ or Quantisal™ II Oral Fluid Collection Device
Target analyte	Oxycodone	Hydrocodone

6. Performance Characteristics

The following laboratory performance studies were performed to determine substantial equivalence of the SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay to the predicate device. Assay performance was established using the Beckman Coulter AU5800 chemistry analyzer.

6.1 Precision

A precision study was performed over 15 days, 2 runs per day with 2 collection devices per run (N=60), one replicate per collection device on 1 lot of reagent and 3 lots of Quantisal™ Oral Fluid Collection Device. Drug free negative oral fluid was spiked to concentrations of assay cutoff and ±25%, ±50%, ±75%, ±100% of the cutoff and was collected using the collection devices. The spiked concentrations were confirmed by mass spectrometry (LC-MS/MS) before collection. The study established the repeatability of the testing system, including assay and oral fluid collection device. Test results in qualitative and semi-quantitative modes are presented in **Table 2** and **Table 3**.

An additional 20-day study was performed on 3 lots of assay reagent to demonstrate the repeatability across multiple reagent lots.

Table 2 – 15 Days Precision -Qualitative- Quantisal™ – All 3 lots

Concentration (ng/mL)	% of cutoff	# of determinations	Results
Quantisal™ Lot 1			
0.0	-100%	60	Negative/100%
7.5	-75%	60	Negative/100%
15	-50%	60	Negative/100%
22.5	-25%	60	Negative/100%
30	Cutoff	60	27 Positive/33 Negative
37.5	+25%	60	Positive/100%
45	+50%	60	Positive/100%
52.5	+75%	60	Positive/100%
60	+100%	60	Positive/100%
Concentration (ng/mL)	**% of cutoff**	**# of determinations**	**Results**
Quantisal™ Lot 2			
0.0	-100%	60	Negative/100%
7.5	-75%	60	Negative/100%
15	-50%	60	Negative/100%
22.5	-25%	60	Negative/100%
30	Cutoff	60	33 positive/27 Negative
37.5	+25%	60	Positive/100%
45	+50%	60	Positive/100%
52.5	+75%	60	Positive/100%
60	+100%	60	Positive/100%
Concentration (ng/mL)	**% of cutoff**	**# of determinations**	**Results**
Quantisal™ Lot 3			

Concentration (ng/mL)	% of cutoff	# of determinations	Results
0.0	-100%	60	Negative/100%
7.5	-75%	60	Negative/100%
15	-50%	60	Negative/100%
22.5	-25%	60	Negative/100%
30	Cutoff	60	27 Positive/33 Negative
37.5	+25%	60	Positive/100%
45	+50%	60	Positive/100%
52.5	+75%	60	Positive/100%
60	+100%	60	Positive/100%

Table 3 - 15 Days Precision -Semi-Quantitative- Quantisal™ – All 3 lots

Concentration (ng/mL)	% of cutoff	# of determinations	Result
Quantisal™ Lot 1			
0.0	-100%	60	Negative/100%
7.5	-75%	60	Negative/100%
15	-50%	60	Negative/100%
22.5	-25%	60	Negative/100%
30	Cutoff	60	43 Positive/ 17 Negative
37.5	+25%	60	Positive/100%
45	+50%	60	Positive/100%
52.5	+75%	60	Positive/100%
60	+100%	60	Positive/100%
Concentration (ng/mL)	**% of cutoff**	**# of determinations**	**Results**
Quantisal™ Lot 2			
0.0	-100%	60	Negative/100%
7.5	-75%	60	Negative/100%

Concentration (ng/mL)	% of cutoff	# of determinations	Result
15	-50%	60	Negative/100%
22.5	-25%	60	Negative/100%
30	Cutoff	60	50 positive/10 Negative
37.5	+25%	60	Positive/100%
45	+50%	60	Positive/100%
52.5	+75%	60	Positive/100%
60	+100%	60	Positive/100%
Concentration (ng/mL)	**% of cutoff**	**# of determinations**	**Results**
Quantisal™ Lot 3			
0.0	-100%	60	Negative/100%
7.5	-75%	60	Negative/100%
15	-50%	60	Negative/100%
22.5	-25%	60	Negative/100%
30	Cutoff	60	52 Positive/8 Negative
37.5	+25%	60	Positive/100%
45	+50%	60	Positive/100%
52.5	+75%	60	Positive/100%
60	+100%	60	Positive/100%

6.2 Specificity and Cross Reactivity

Structurally and functionally similar compounds were spiked into drug free pooled oral fluid at levels that will yield a result that is equivalent to the cutoff, if cross reacting. The study verified the cross reactivity of the hydrocodone assay to related drugs and drug metabolites, in both the qualitative and semi-quantitative modes. Cross-reactivity test results in qualitative mode and semi-quantitative mode are presented in **Table 4** below.

Table 4 – Cross Reactivity – Qualitative and Semi-Quantitative

Compound	Analyte Conc. (ng/mL)	Hydrocodone Conc. (ng/mL)	Hydrocodone Semi-Quantitative Mean Value (ng/mL)	Hydrocodone Qualitative Result	Cross Reactivity (%)
6-Acetylcodeine	40,000	30	15.9	Negative	<0.1%
6-Acetylmorphine	40,000	30	18.3	Negative	<0.1%
Buprenorphine	40,000	30	4.2	Negative	<0.1%
Dextromethorphan	40,000	30	10.7	Negative	<0.1%
Fentanyl	40,000	30	5.2	Negative	<0.1%
Heroin	40,000	30	11.0	Negative	<0.1%
(+) Methadone	40,000	30	5.4	Negative	<0.1%
Morphine-6β-D-Glucuronide	40,000	30	4.6	Negative	<0.1%
Norbuprenorphine	40,000	30	5.6	Negative	<0.1%
Norcodeine	40,000	30	8.6	Negative	<0.1%
Normorphine	40,000	30	7.5	Negative	<0.1%
Tapentadol	40,000	30	4.8	Negative	<0.1%
Meperidine	40,000	30	5.4	Negative	<0.1%
Tramadol	40,000	30	5.3	Negative	<0.1%
Codeine	30,000	30	30.4	Positive	0.1%
Levorphanol	4,000	30	30.3	Positive	0.8%
Noroxycodone	16,500	30	30.1	Positive	0.2%
Noroxymorphone	19,000	30	30.8	Positive	0.2%
Oxycodone	2,000	30	30.6	Positive	1.5%
Dihydrocodeine	1,800	30	31.2	Positive	1.7%
Morphine	32,000	30	30.9	Positive	0.1%
Desomorphine	225	30	32.9	Positive	13.3%
Morphine-3β-D-Glucuronide	19,000	30	31.0	Positive	0.2%
Nalorphine	39,000	30	31.5	Positive	0.1%
Norhydrocodone	1,900	30	31.3	Positive	1.6%
Oxymorphone	2,000	30	30.8	Positive	1.5%
Hydromorphone	34	30	31.9	Positive	88.2%
Hydromorphone-3β-D-Glucuronide	20	30	31.4	Positive	150.0%
Naloxone	2,000	30	30.4	Positive	1.5%

Compound	Analyte Conc. (ng/mL)	Hydrocodone Conc. (ng/mL)	Hydrocodone Semi-Quantitative Mean Value (ng/mL)	Hydrocodone Qualitative Result	Cross Reactivity (%)
Naltrexone	13,000	30	31.1	Positive	0.2%
Oxymorphone-3β-D-Glucuronide	1,500	30	31.0	Positive	2.0%

6.3 Interference – Structurally Unrelated Compounds

Structurally unrelated compounds were evaluated in qualitative and semi-quantitative modes by spiking the potential interferent into drug free oral fluid containing hydrocodone at ±25% of the cutoff. At the levels tested, there was no interference with structurally unrelated compounds. The concentration levels of structurally unrelated compounds are presented in **Table 5.**

Table 5 - Non-Interfering Structurally Unrelated Compounds

Compound	Concentration Tested (ng/mL)
7-Aminoclonazepam	5,000
7-Aminoflunitrazepam	40,000
7-Aminonitrazepam	40,000
α-Hydroxyalprazolam	40,000
Alprazolam	40,000
Amitriptyline	40,000
Amobarbital	40,000
(+)S-Amphetamine	40,000
Atomoxetine	40,000
Barbital	40,000
Benzoylecgonine	40,000
Benzylpiperazine	40,000
Bromazepam	40,000
Brompheniramine	40,000
Buprenorphine	40,000
Bupropion	40,000
Butabarbital	40,000

Compound	Concentration Tested (ng/mL)
Butalbital	40,000
Cannabidiol	40,000
Cannabinol	40,000
Carbamazepine	40,000
Carisoprodol	40,000
Cetirizine	40,000
Chlordiazepoxide	40,000
1-(3-Chlorophenyl)piperazine (mCPP)	40,000
Chlorpromazine	40,000
Chlorpheniramine	40,000
Cimetidine	40,000
cis-Tramadol	40,000
Citalopram	40,000
Clobazam	40,000
Clomipramine	40,000
Clonazepam	40,000
Clozapine	20,000
Cocaine	40,000
Cyclobenzaprine	40,000
Dehydronorketamine	10,000
Demoxepam	40,000
Desalkylflurazepam	40,000
Desipramine	40,000
Diazepam	40,000
Digoxin	40,000
(±)-10,11-Dihydro-10-Hydroxycarbamazepine	40,000
Diphenhydramine	40,000
Doxepin	40,000
Doxylamine	40,000
Duloxetine	40,000

Compound	Concentration Tested (ng/mL)
Ecgonine	40,000
Ecgonine Methyl Ester	40,000
EDDP	40,000
EMDP	40,000
1R,2S(-)-Ephedrine	40,000
1S,2R(+)-Ephedrine	40,000
Ethotoin	40,000
Ethylmorphine	5,000
Ethyl-β-D-Glucuronide	40,000
Fenfluramine	40,000
Flunitrazepam	40,000
Fluoxetine	40,000
Flurazepam	40,000
Haloperidol	40,000
Hexobarbital	40,000
Gabapentin	40,000
Imipramine	40,000
Ketamine	40,000
Lamotrigine	40,000
Labetalol	40,000
Lidocaine	40,000
Lorazepam	40,000
Lorazepam Glucuronide	15,000
Loratadine	40,000
Lormetazepam	40,000
LSD	40,000
Maprotiline	40,000
(±)MDA	40,000
(±)MDEA	40,000
(±)MDMA	40,000

Compound	Concentration Tested (ng/mL)
Meprobamate	40,000
(+)S-Methamphetamine	40,000
Methaqualone	40,000
Methoxetamine	40,000
Methylone	40,000
Methylphenidate	40,000
α-Methyl-α-phenylsuccinimide	40,000
Mirtazapine	40,000
Naproxen	40,000
n-desmethylcitalopram	40,000
n-desmethyltapentadol	40,000
Nitrazepam	40,000
Nordiazepam	40,000
(±)Norketamine	40,000
Normesuximide	40,000
(±)Norpropoxyphene	40,000
Nortriptyline	40,000
Olanzapine	40,000
Oxazepam	40,000
PCP	40,000
Pentazocine	40,000
Pentobarbital	40,000
Phenazepam	40,000
Phenobarbital	40,000
Phentermine	40,000
(±)Phenylpropanolamine (PPA)	40,000
Phenytoin	40,000
PMA	40,000
PMMA	40,000
Prazepam	40,000

Compound	Concentration Tested (ng/mL)
Procaine	40,000
(±)Propoxyphene	35,000
Propranolol	40,000
Protriptyline	40,000
R(-)-Phenylephrine	40,000
R,R(-)-Pseudoephedrine	40,000
Risperidone	40,000
Ritalinic Acid	40,000
S,S(+)-Pseudoephedrine	40,000
Salicylic Acid	40,000
Secobarbital	40,000
Sertraline	40,000
Sufentanil	40,000
Temazepam	40,000
(-)11-nor-9-carboxy-Δ9-THC	40,000
(-)-Δ9-THC	40,000
(±)-11-hydroxy-Δ9-THC	40,000
Theophylline	40,000
Thioridazine	10,000
Trazodone	40,000
Triazolam	40,000
3-Trifluoromethylphenylpiperazine	40,000
Trimipramine	40,000
Tyramine	40,000
Venlafaxine	40,000
Verapamil	40,000
Zolpidem	40,000
2-CB(4-bromo-2,5-dimethoxyphenyl-benzeneethamine)	40,000
Midazolam	40,000
Oxazepam Glucuronide	35,000

Compound	Concentration Tested (ng/mL)
Norpseudoephedrine	7500
O-desmethylvenlafaxine	40,000
N-desmethylvenlafaxine	40,000
N-desmethyltramadol	40,000
O-desmethylcistramadol	40,000

6.4 Interference – Endogenous Compounds and Exogenous Compounds

Endogenous and commonly ingested exogenous compounds were assessed using qualitative and semi-quantitative methods by spiking potential interferents into drug-free oral fluid containing hydrocodone at ±25% of the cutoff concentration. Additionally, oral products were evaluated by collecting oral fluid samples from volunteers using the Quantisal™ Oral Fluid Collection Device after product use. No interference was observed from endogenous substances, exogenous compounds, or orally administered products at the tested levels. Endogenous compounds and exogenous compounds are presented in **Table 6**, **Table 7** and **Table 8.**

Table 6 – Non-Interfering Endogenous Compounds

Compound	Concentration Tested
Ascorbic Acid	3 mg/mL
Bilirubin	0.15 mg/mL
Cholesterol	0.45 mg/mL
γ-globulin	0.8 mg/mL
Hemoglobin	3 mg/mL
Human Serum Albumin (HSA)	15 mg/mL
IgA	1 mg/mL
IgG	1 mg/mL
IgM	0.5 mg/mL
Salivary-α-amylase	1000 U/mL

Table 7 – Non-Interfering Exogenous Compounds (Commonly Ingested)

Compound	Concentration Tested
Acetaminophen	0.05 mg/mL
Acetylsalicylic Acid	0.1 mg/mL
Baking Soda	0.6% v/v
Cotinine	0.03 mg/mL
Denture Adhesive	0.6% w/v
Ibuprofen	0.05 mg/mL
Alcohol (Ethanol)	6% v/v
Caffeine	0.05 mg/mL
Coffee	6% v/v
Cranberry Juice	6% v/v
Milk	2% v/v
Mouthwash	6% v/v
Orange Juice	6% v/v
Soft Drink (Pepsi)	6% v/v
Sodium Chloride	18 mg/mL
Tea	6% v/v
Toothpaste	6% w/v
Sugar	30 mg/mL

Table 8 – Non-Interfering Orally Used Exogenous Products

Product	Quantity Ingested
Teeth Whitener	2 strips
Cigarette	1 cigarette
Hard Candy	1 piece
Chewing Gum	1 piece
Sugar	2 teaspoon
Cough Syrup	2 teaspoon
Milk	100 mL
Orange Juice	100 mL
Hydrogen Peroxide (3% OTC)	10 mL
Ibuprofen	200 mg
Acetaminophen	1000 mg

6.5 Interference – pH

To evaluate potential interference from the effect of oral fluid pH, device performance in the qualitative and semi-quantitative modes was tested using a range of oral fluid pH values (3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 and 11.0). All test samples were prepared in drug free oral fluid containing hydrocodone at ±25% of the cutoff. At the pH levels tested, there was no interference observed for each test mode.

6.6 Linearity/Recovery

Linearity of the SEFRIA™ Hydrocodone Oral Fluid Immunoassay in semi-quantitative mode was assessed by spiking pooled drug-free oral fluid with a high concentration of hydrocodone. Serial dilutions were performed using drug-free oral fluid to generate specimens with target concentrations ranging from 10 ng/mL to 110 ng/mL. A 0 ng/mL sample was prepared using unspiked drug-free oral fluid. Each concentration level was collected using Quantisal™ Oral Fluid Collection Devices and tested in five replicates. Mean values from replicate testing were used to

calculate recovery. The assay demonstrated acceptable linearity and recovery across the tested concentration range. Results are summarized in **Table 9**. The linear range of the assay was confirmed to be 10 – 100 ng/mL using Quantisal™ Oral Fluid Collection Device, and the drug recovery was within the ±15% of the expected value.

Table 9 - Linearity/Recovery – Quantisal

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	4.6	N/A
10	11.3	113.2
20	19.7	98.6
30	27.5	91.5
40	34.4	86.1
50	45.3	90.7
60	52.9	88.2
70	68.7	98.1
80	77.7	97.1
90	99.6	110.6
100	90.9	90.9
110	103.6	94.2

6.7 Hydrocodone Stability in Oral Fluid

The stability of hydrocodone in the oral fluid specimens collected with the Quantisal™ and Quantisal™ II Oral Fluid Collection Device was evaluated with low positive samples (+50% cutoff) at room temperature (8-25°C) and refrigerated (2-8°C). Sample stability testing was performed using LCMS/MS or GC/MS at multiple timepoints post collection at 8°C - 25°C and at 2°C - 8°C. The stability study results demonstrate that oral fluid samples containing hydrocodone are stable at 2°C - 8°C for up to 12 months and 10 days at ambient temperature 8°C - 25°C when stored in

Quantisal™ or Quantisal™ II Oral Fluid Collection Device. The data to support hydrocodone sample stability was submitted and cleared in K223781 (Quantisal™ II) and K232898 (Quantisal™).

6.8 Calibration Duration

To evaluate calibration stability, drug-free oral fluid samples were spiked with hydrocodone at ±25% of the cutoff concentration and tested in both qualitative and semi-quantitative modes over a 15-day period. At the initial time point, a two-point calibration curve was established in qualitative mode and five-point calibration curve was established in semi-quantitative mode. These calibrations were used through the duration of the study. The test results met acceptance criteria at each time point up to 15 days, providing a validated margin beyond the claimed duration without extrapolation. The calibration duration stability study confirmed that the SEFRIA™ Hydrocodone Oral Fluid Immunoassay supports a calibration interval of up to 14 days.

6.9 Method Comparison

A method comparison study was conducted to evaluate the analytical performance of the SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay using the Beckman Coulter AU5800 analyzer, compared to the reference method, Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS). A total of eighty (80) deidentified, unaltered clinical oral fluid samples (40 positive, 40 negative) were tested. Qualitative concordance was 100% for positive samples and 92.5% for negative samples. Semi-quantitative concordance was 97.5% for positives and 95% for negatives. Discordant results were limited and primarily attributed to cross-reactivity or concentrations near the assay cutoff.

Table 10 – Method Comparison

SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay	LC-MS/MS Hydrocodone Concentration				Agreement (%)
	< 15 ng/mL (Less than	15 to <30 ng/mL	≥30 to 45 ng/mL	>45 ng/mL (Greater	

		-50% cutoff)	(Between -50% cutoff and cutoff)	(Between cutoff and +50% cutoff)	than +50% cutoff)	
Qualitative	Positive	2	1	4	36	100.0
	Negative	34	3	0	0	92.5
Semi-Quantitative	Positive	2	0	3	36	97.5
	Negative	34	4	1	0	95.0

Table 11 – SEFRIA™ Hydrocodone Method Comparison Discordant Results

Discordant Result Summary at 30 ng/mL Cutoff				
Sample ID	**Concentration (LCMS)**	**LCMS Qualitative Result**	**SEFRIA™ Qualitative Result (POS/NEG)**	**SEFRIA™ Semi-Quantitative Result (POS/NEG)**
HYC-0319	10.3962	NEG	POS	POS
HYC-0324	0	NEG	POS	POS
HYC-0327	21.996	NEG	POS	NEG
HYC-0355	30.4135	NEG	POS	NEG

7. Conclusion

The information provided in this pre-market notification demonstrates that the SEFRIA™ Hydrocodone Oral Fluid Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device.