

ARK™ Fentanyl II Assay

Siemens Atellica® CH Analyzer

For In Vitro Diagnostic Use

The ARK Fentanyl II Assay is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers. This *in vitro* diagnostic device is for prescription use only.

The ARK Fentanyl II Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

Please review **IMPORTANT INFORMATION** below. Refer to applicable package inserts for information regarding intended use, reagent storage, specimen handling, calibration, quality control and other required information. ARK package inserts for reagent, calibrator, and control are available online at www.ark-tdm.com.

MANUFACTURER INFORMATION

ARK Fentanyl II reagents, ARK Fentanyl calibrators, and ARK Fentanyl controls are manufactured by ARK Diagnostics, Inc. and sold/distributed by Siemens Healthcare Diagnostics for application on the Siemens Atellica® CH Analyzer.

ARK Diagnostics, Inc.
48089 Fremont Boulevard
Fremont, CA 94538
www.ark-tdm.com

ORDERING INFORMATION

For orders and technical support, contact Siemens Healthcare Diagnostics.

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
Siemens.com/healthineers

Technical Support for USA and Canada:
1-877-229-3711

Ordering for USA:
1-888-588-3916

Ordering for Canada:
1-800-615-2615

In other countries, please contact your local representative.

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Product Name	Quantity/Kit	ARK Product Number	Siemens Material Number (SMN)
ARK™ Fentanyl II Assay	R1 28mL, R2 28mL	5069-0001-00	11554027
ARK™ Fentanyl II Assay	R1 115mL, R2 115mL	5069-0001-01	11554028
ARK™ Fentanyl II Assay	R1 500mL, R2 500mL	5069-0001-02	11554029
ARK™ Fentanyl Calibrator	2 x 10mL; Negative	5031-0002-01	11354475
ARK™ Fentanyl Calibrator	2 x 10mL; Cutoff	5031-0002-02	11354476
ARK™ Fentanyl Control	2 x 10mL; Low 2 x 10mL; High	5031-0003-00	11354477
EMPTY reagent pack	4 P1 Packs & 4 P2 Packs	N/A	11097534
Atellica CH EMPTY1	8 P1 Packs	N/A	11538114
Atellica CH EMPTY2	8 P2 Packs	N/A	11538115

PREPARATION OF ASSAY COMPONENTS

The following assay components are ready-to-use liquids as supplied. When not in use, store upright at 2-8°C. Components are stable until the expiration date printed on the label if stored as directed.

Reagent R1: Antibody/Substrate (23 mL) and **Reagent R2:** Enzyme (23 mL). Transfer the respective reagent volume into the appropriate size reagent bottle (EMPTY reagent pack). Mark the label on the bottle with the reagent name and expiration date.

Precaution: Avoid cross-contamination of R1 and R2.

Calibrators and Controls: Supplied separately. Perform assay-specific calibration and quality control as recommended.

EMPTY Reagent Packs: Supplied separately by Siemens. The reagent pack must be manually loaded on the Siemens Atellica® CH Analyzer. Manually fill the EMPTY reagent packs with R1 and R2. Refer to the online help for instructions on loading operator-filled empty reagent packs.

SPECIMEN COLLECTION AND PREPARATION

Refer to the ARK Fentanyl II Assay package insert for information on specimen collection and preparation.

IMPORTANT INFORMATION

ARK Diagnostics, Inc. manufactures the ARK Fentanyl II Assay, ARK Fentanyl Calibrators and ARK Fentanyl Controls and is solely responsible for the quality of the data obtained which is caused by performance of the reagents, any variation between lots of ARK reagents, ARK calibrators or ARK controls. ARK Diagnostics, Inc. is not responsible for user-defined changes. It is the responsibility of the user to validate any modifications to the parameters defined in this application sheet and their impact on all assay results.

TECHNICAL PERFORMANCE EVALUATION

Performance characteristics on the Siemens Atellica® CH Analyzer were consistent with package insert information for the ARK Fentanyl II Assay. All data were obtained on a Siemens Atellica® CH Analyzer. Data available upon request.

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INSTRUMENT PARAMETERS: SIEMENS ATELICA® CH ANALYZER

The following are parameters for use when performing the ARK Fentanyl II Assay on the Siemens Atellica® CH Analyzer. Instrument operating instructions are contained in the Siemens Atellica® Operator's Manual.

Contents	Pack Volume (mL)	Number of Tests
Reagent 1: Pack 1, Well 1	23 mL*	260
Reagent 2: Pack 2, Well 1	23 mL*	260

*Do not exceed required fill volume.

Calibration and Onboard Reagent Stability	
LOT CAL INTERVAL	60 Days**
ONBOARD STABILITY	60 Days**
PACK CAL INTERVAL	14 Days**

**Days listed are based on data collected from validation of the ARK Fentanyl II Assay on the Siemens Atellica® CH Analyzer. Refer to the ARK Fentanyl II Assay package insert for instructions on when to re-calibrate.

Parameter	Atellica
R1 volume	60
R2 volume	60
Serum reac.s.vol	23
predilution.s.vol	50
predilution	100
Reaction time	7
Reagent 1 stir	MixerMediumMixCmd
Reagent 2 stir	MixerFastMixCmd
Name	FEN2
Decimal Places	0
Common Unit	Qual
SI Unit	Qual
M-wave.L.	340
S-wave.L.	410
Analy.mthd	Rate
Calc.mthd	Qualitative
Threshold Value	1000

Results

Results are reported as a normalized rate, a factor is calculated to adjust the cutoff calibrator to 1000.

- Samples ≥ 1000 will report as +++Qual with an Interpretation of POS;
- Samples < 1000 will report as ---Qual with an Interpretation of NEG.

Assay	TDEF Code	Time to First Result
FEN2	4084	7 minutes

Calibration

Prepare a calibration by using the Calibrator B (Cutoff) listed in the table below. Run controls. Recalibrate as indicated by control results.

Assay	Cal B
FEN2	1.0 ng/mL

Parameter	Atellica
Measurement Times	Seconds
MNRead_x1	330.83
MNRead_x2	339.75
MNRead_x3	348.67
MNRead_x4	357.59
MNRead_x5	366.51
MNRead_x6	375.43
MNRead_x7	384.35
MNRead_x8	393.27
MNRead_x9	402.19
MNRead_x10	411.11
Calibrator Predilution	μL sample/μL Diluent
CAL B	50/100
Sample Type	Urine

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Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue, Tarrytown, NY 10591
Siemens.com/healthineers