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Attorneys for Plaintiff ARK Diagnostics, Inc.

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

EASTERN DIVISION

16 ARK DIAGNOSTICS, INC., a
17 California Corporation

18
19 Plaintiff,

20 v.

21 ACRO BIOTECH, INC., a California
22 Corporation, HANGZHOU ALLTEST
23 BIOTECH CO., LTD., and DOES 1-
24 10, inclusive

25 Defendants.
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27
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Case No. 5:21-cv-00871

**COMPLAINT FOR INFRINGEMENT
OF U.S. PATENT NO. 10,203,345**

JURY TRIAL DEMANDED

1 Plaintiff ARK Diagnostics, Inc. (“ARK” or “Plaintiff”) states and alleges as
2 follows:

3 **SUMMARY OF THE DISPUTE**

4 1. This is an action for patent infringement arising under the patent laws of
5 the United States of America, including specifically 35 U.S.C. § 271(a)-(c), based on
6 Defendants Hangzhou AllTest Biotech Co., Lt. (“AllTest”) and Acro Biotech, Inc.’s
7 (“Acro”) (collectively, “Defendants”) willful infringement of United States Patent
8 No. 10,203,345 (the “’345 Patent) by the unauthorized use, offer for sale, sale, and/or
9 importation of Defendants’ infringing gabapentin immunoassay rapid drug tests
10 accused below (“the Accused Product”), and by their inducement of and contribution
11 to infringement of the ’345 Patent.

12 2. ARK is a pioneer in the therapeutic drug monitoring (“TDM”) and urine
13 drug testing (“UDT”) markets, which include assays and tests to detect and monitor
14 the presence of therapeutic and illicit drugs and other small molecules. Since its
15 incorporation in 2003, ARK’s mission has been to improve healthcare through the
16 design, research and development, manufacture, and distribution of in vitro diagnostic
17 (“IVD”) immunoassays for TDM and UDT. ARK’s innovations include its
18 homogeneous enzyme immunoassay technology, which it introduced for the next
19 generation of clinical laboratory testing. This technology includes the ARK
20 Gabapentin Assay, an immunoassay capable of rapidly detecting the presence of
21 gabapentin, an entirely new field in the TDM and UDT markets. The ’345 Patent
22 protects the ARK Gabapentin Assay.

23 3. The products and processes covered by the ’345 Patent relate to
24 immunoassays for detecting the presence of gabapentin in a biological sample.
25 Gabapentin (trade name Neurontin) is a chemical compound used as an anti-seizure
26 and anti-convulsant medication that has the following chemical structure:
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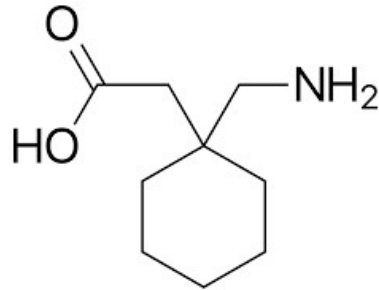


Figure 1 – Chemical Structure of Gabapentin

4. Patients can metabolize gabapentin at different rates. As a result, two patients who receive the same dose of gabapentin may experience different levels of serum drug concentration, which will result in inconsistent therapeutic effects. Thus, monitoring a patient's concentration level of gabapentin is essential to determining the correct dosage to prescribe.

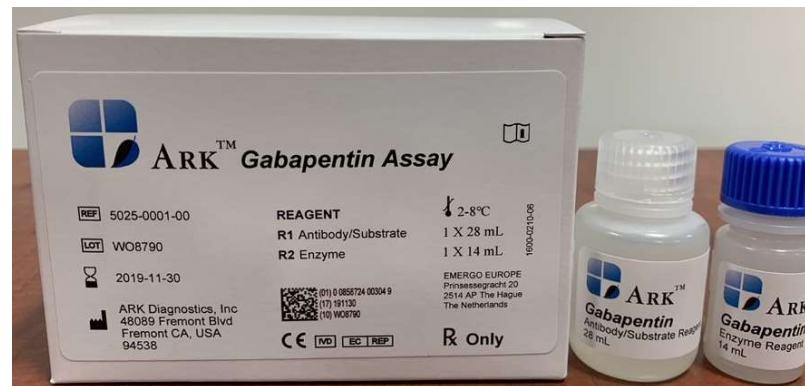
5. Apart from its therapeutic uses, gabapentin has become popular as a drug of abuse, which users take in tandem with opioids to increase their potency.¹ When abused with opioids, gabapentin increases the risk of respiratory problems and fatal overdose.² The growing abuse of gabapentin has led to demand for quick, accurate, and inexpensive methods for testing the presence of gabapentin in a test subject's biological sample.

6. ARK researched, developed, and invented novel methods and compounds for assaying gabapentin that can be used to test for the presence of gabapentin quickly, accurately, and inexpensively. ARK's gabapentin immunoassay products use antibodies, enzymes, and a substrate to test for the presence of gabapentin and gabapentin conjugates in a biological sample. When gabapentin is absent from a

¹ See Alyssa M. Peckham et. al., *Gabapentin use, abuse, and the US opioid epidemic: the case for reclassification as a controlled substance and the need for pharmacovigilance*, 11 RISK MANAG. HEALTHCARE 11, 109, 110 (2018), www.ncbi.nlm.nih.gov/pmc/articles/PMC6103607/pdf/rmhp-11-109.pdf.

² *Id.* at 109; *FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)*, FDA (last updated Jan. 30, 2020), www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-

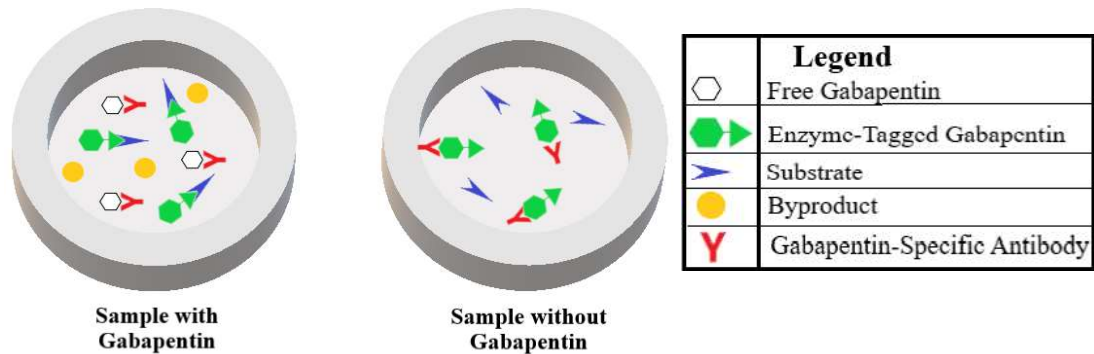
1 sample, the gabapentin-specific antibody binds to the enzyme, preventing the enzyme
 2 from producing NADH. Conversely, when gabapentin is present, the antibody binds
 3 to the gabapentin, allowing the enzyme to bind to the substrate and produce NADH.
 4 NADH levels can then be measured and used to determine the presence and
 5 concentration of gabapentin.



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13 *Figure 2 - ARK Gabapentin Assay, which includes*
 14 *Reagent R1 – Antibody/Substrate; and Reagent R2 – Enzyme.*

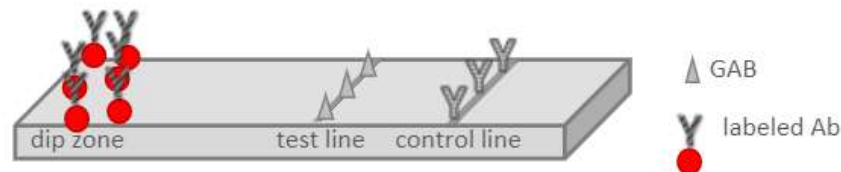
15 7. ARK’s Gabapentin Assay can be used with clinical analyzers to test for
 16 the presence and concentration levels of gabapentin and gabapentin conjugates in a
 17 patient’s biological sample. To do so, a known quantity of Reagent R1 is mixed with
 18 the biological sample. Reagent R1 contains rabbit polyclonal antibodies that
 19 specifically bind to gabapentin as well as nicotinamide adenine dinucleotide (“NAD”).
 20 If the sample contains gabapentin, Reagent R1’s antibodies will bind to the free
 21 gabapentin. When Reagent R2 is introduced, these bound antibodies will not be free to
 22 bind to the enzyme-tagged gabapentin. Reagent R2 contains gabapentin conjugated at
 23 the carboxyl group to bacterial glucose-6-phosphate dehydrogenase (“G6PDH”).
 24 When G6PDH is active, it converts NAD to NADH, which changes the way the
 25 solution absorbs light. Conversely, if the sample does not contain gabapentin, Reagent
 26 R1’s antibodies will bind to Reagent R2’s enzyme-tagged gabapentin, in turn
 27 inhibiting production of NADH. A spectrometer can measure this change in
 28

1 absorbance with enough specificity to allow users to determine appropriate dosage
2 rates.



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10 *Figure 3 - Diagram of ARK Gabapentin Assay's Response to Different Samples*

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12 8. In addition to use with a clinical chemistry analyzer, ARK's gabapentin-
13 specific antibodies can be and are used in competitive lateral flow test strips in cups,
14 dip-cards, and other test formats for performing rapid drug tests without using
15 specialized equipment. Lateral flow tests include gabapentin antibodies deposited on
16 the test's "dip zone" that are designed to bind with gabapentin and specific gabapentin
17 conjugates. In these lateral flow tests, the gabapentin antibodies are labeled with a
18 marker, such as a gold microparticle, that becomes visible to the naked eye when
19 antibodies concentrate in a small enough area. Gabapentin lateral flow tests also
20 include a "test line" that includes unbound gabapentin molecules and a "control line"
21 that includes gabapentin antibodies that bind with excess labeled antibody.



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25 *Figure 4 - Diagram of Gabapentin Lateral Flow Test*

26 9. When a biological sample, such as a blood or urine sample, is added to
27 the dip zone, the sample diffuses along the strip, carrying the gabapentin antibodies. A
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