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13 IN THE UNITED STATES DISTRICT COURT

14 EASTERN DISTRICT OF CALIFORNIA

15 UNITED STATES OF AMERICA,

CASE NO. 1:23-CR-00219-NODJ-BAM

16 Plaintiff,

GOVERNMENT'S RESPONSE TO
DEFENDANT'S MOTION FOR BAIL REVIEW

v.

DATE: April 24, 2024

17 JIA BEI ZHU, aka JESSE ZHU, QIANG HE,
18 and DAVID HE,

TIME: 2:00 p.m.

19 Defendant.

COURT: Hon. Erica P. Grosjean

20 The United States of America, by and through its attorneys, Phillip A. Talbert, United States
21 Attorney, and Joseph Barton, Arelis Clemente, and Henry Z. Carbajal III, Assistant United States
22 Attorneys, hereby provides its response to defendant's motion for bail review.

23 **I. INTRODUCTION**

24 **A. Procedural History**

25 On November 16, 2023, Jia Bei Zhu ("Zhu") was indicted on two counts of distribution of
26 adulterated and misbranded medical devices and one count of making false statements to United States
27 Food and Drug Administration ("FDA") officials. (Dkt. No. 14). At his arraignment, Zhu entered a not
28 guilty plea. He made two requests to continue his detention hearing, which took place on November 22,
2023. At his detention hearing, in light of the Pretrial Services Office's detention recommendation, Zhu
submitted on the issue of detention and was detained as a risk of flight and obstruction of justice. (Dkt.

1 No. 19). On April 18, 2024, Zhu filed the instant Motion for Bail Review. (Dkt. No. 45).

2 **B. Relevant Background**

3 During the past several years, Zhu lived and operated businesses in Canada and the United States
4 under a different alias. In approximately 2014, after having civil legal troubles in Canada with his
5 business IND Diagnostic Incorporated, Zhu moved to the United States and has since resided here. Zhu
6 had little difficulty entering the United States, as he has Canadian citizenship and had Canadian
7 identification documents, including a Canadian Driver's License and a Canadian passport. (Ex. 1, Zhu
8 Canadian information).¹ By 2015, Zhu was opening bank accounts and establishing businesses in the
9 United States. In 2021, Zhu used the name Qiang He to apply for asylum and filed a personal statement
10 and a copy of a Chinese passport in support of his application. (Dkt. No. 45 , Ex. B, at 2). After
11 submitting his application for asylum, Zhu filed an application to change his name from Qiang He to
12 David He, using an apparent Chinese passport issued to Qiang He. (Dkt. No. 45, Ex. C, at 2, Ex. ,B at
13 2). As David He, Zhu obtained a Social Security number, an employment authorization, and an official
14 California Identification card for his alias. On January 23, 2024, the United States Department of
15 Homeland Security conducted a fingerprint analysis comparing the fingerprints obtained from Zhu's
16 prior entries into the United States with David He's fingerprints obtained from his arrest/booking by the
17 United States Marshals Service and found the fingerprints were a match and made by the same
18 individual.

19 Zhu has maintained ties with China while living in the United States. He owned and operated a
20 business named Ai De Diagnostics out of China since at least 2016. (Ex. 2, Redacted 2016 FDA
21 inspection report). Notably, income generated from this Chinese-based business supplied the funding
22 for the purchase of the Sugar Springs Las Vegas property Zhu now offers for bond. (Ex. 3, Wire
23 Transfer for Sugar Springs). Ai De Diagnostics also provided funds at various times to Zhu's other
24 businesses Universal Meditech Incorporated ("UMI"), Prestige Biotech Incorporated ("PBI"), and David
25 Destiny Discovery, LLC ("3D"); businesses Zhu now claims are owned and operated by someone else.²
26 In addition, Zhaoyan Wang ("Ms. Wang"), the mother of Zhu's infant son, Ms. Wang's mother, and

27 ¹ Zhu's Canadian passport is expired as of September 2023.

28 ² On April 13, 2024, Ms. Wang and two other individuals became 3D's managing members.

1 Zhu's infant son flew to China six days after service of a search warrant in this case and have not
 2 returned. Zhu also has a brother in New Zealand and an ex-wife and children in Canada. Thus, Zhu's
 3 business operations and his closest family are outside the United States.

4 **II. APPLICABLE LAW**

5 **A. Standard for Bail Review**

6 A bail hearing "may be reopened, before or after a determination by the judicial officer, at any
 7 time before trial if the judicial officer finds that information exists that was *not known to the movant* at
 8 the time of the hearing and that has a material bearing on the issue whether there are conditions of
 9 release that will reasonably assure the appearance of such person as required and the safety of any other
 10 person and the community." 18 U.S.C. § 3142(f) (emphasis added). The rationale behind this provision
 11 is that "a rule that would not discourage a party for failing to acquire *readily available evidence* for
 12 presentation the first time is a rule that encourages piecemeal presentations. Judicial efficiency is not
 13 served by such a practice." *United States v. Tommie*, No. CR-10-1578-PHX-SRB, 2011 WL 2457521,
 14 at *2 (D. Ariz. June 20, 2011) (citations omitted, emphasis in original).

15 **B. Pertinent Bail Principles**

16 Zhu's proposal of spare rental properties for bond and third-party custodians does not address the
 17 typical purposes of conventional bail conditions. First, "[t]he purpose of bail is not served unless losing
 18 the sum would be a deeply-felt hurt to the defendant and his family; the hurt must be so severe that
 19 defendant will return for trial rather than flee." *United States v. Townsend*, 897 F.2d 989, 996 (9th Cir.
 20 1990) (citation omitted). Rental and investment properties posted by strangers or sourced from
 21 unnamed "family funds from China" do not fulfill the purposes of the Bail Reform Act. (Dkt. 45-4, ¶¶
 22 3(c) & 4).³ Secondly, with respect to Zhu's offer of electronic monitoring, in this District location
 23 monitoring is limited to RF rather than GPS. It ensures only a "reduced head start should a defendant
 24 decide to flee." See *United States v. Githens*, Case No. 1:23-CR-00089-ADA-BAM, 2023 WL 4424555,

25
 26 ³ Ms. Wang's vague declaration regarding how 3D is funded and how it holds the property also
 27 fails to comport with Federal Rule of Criminal Procedure 46(e). See *United States v. Noriega-Sarabia*,
 28 116 F.3d 417, 420 (9th Cir. 1997) ("case law makes clear that sureties must reveal their property
 resources so that the government can be assured of their financial ability and so that the court can be
 satisfied that they have an incentive and purpose to secure the defendant's presence at trial") (citations
 omitted).

1 at *3 (E.D. Cal., July 10, 2023). Moreover, location monitoring does not address the risk of obstruction,
 2 as “it provides little to no information about what [defendant] is doing and who he is communicating
 3 with[.]” *United States v. Cazares*, 445 F. Supp. 3d 425, 433 (N.D. Cal. 2020).

4 **III. ZHU SHOULD CONTINUE TO BE DETAINED AS A RISK OF FLIGHT AND**
 5 **OBSTRUCTION OF JUSTICE**

6 **A. Bail Hearing is Not Warranted**

7 A bail hearing is not warranted because Zhu’s motion does not mention any new information not
 8 known to him at the time of the prior detention hearing that is material to the issue of detention. Zhu
 9 states he applied for asylum, changed his name, has an infant son with Ms. Wang and claims financial
 10 resources for posting bond. However, all this information was known to Zhu at the time of his detention
 11 hearing on November 22, 2023. In fact, Zhu applied for asylum in February 2021, changed his name in
 12 August 2021, and his infant son was born in April 2023. Zhu failed to disclose this information to
 13 Pretrial Services and the dates in which these matters took place clearly indicates he was aware of this
 14 information prior to his first detention hearing. Moreover, Ms. Wang’s reference to their special
 15 agreement to keep their family status secret and this being some sort of cultural tradition is non-sensical.
 16 (Dkt. No. 45, Ex. D, ¶ 2).

17 Zhu also knew of 3D and its rental properties during his first detention hearing because he
 18 initially founded 3D and his Chinese company Ai De Diagnostics wired \$850,000 for the purchase of
 19 the Sugar Springs property. (Ex. 3). Rather, it appears Zhu tried to hide these properties and his
 20 business assets. Given that those efforts have been unsuccessful, Zhu now characterizes the properties
 21 and businesses as belonging to others that charitably offer them for his bail. Even if this were the case,
 22 loss to 3D would not be loss to Zhu and thus is not adequate compulsion for Zhu to stay in the country
 23 and face the charges. *See Townsend*, 897 F.3d at 996. Similarly, Zhu proposes third-party custodians.
 24 However, the condition of a third-party custodian was previously considered by Pretrial Services and
 25 found inadequate to address the risk factors. Therefore, with no new information on the matter, no new
 26 consideration is necessary.

27 Zhu also claims he is not a flight risk because he is pursuing civil lawsuits. (Dkt. No. 45 at 5, ¶
 28 4). These are immaterial because not only can they be dismissed at any time but Zhu’s participation in

1 these lawsuits and funding is unclear. For example, it is unclear how UMI's commercial leasing
2 agreement pertains to Zhu. This lack of clarity diminishes Zhu's claim that the lawsuits are material to
3 the flight risk and obstruction of justice consideration. (Dkt. No. 45, Ex. F, ¶ 4).

4 **B. Zhu's Continued Efforts at Deception Calls for Continued Detention**

5 Zhu has continued to mislead the Court and Pretrial Services as to his identity, family ties, assets,
6 and employment. For instance, Zhu provides no reasonable explanation for the misrepresentations he
7 previously made to Pretrial Services during his interview, including his failure to disclose his United
8 States Citizen infant son and the financial resources to post a bond. Therefore, Zhu's assertions that he
9 will not flee should be disregarded and his conduct may support a later finding of obstruction. *See*
10 *United States v. Kesoyan*, Case No. 2:15-CR-236-GEB, 2018 WL 1212527, at *11 (E.D. Cal., Mar. 8,
11 2018) ("Defendant's manifested dishonesty in the record, combined with her access to hidden assets and
12 her ties outside the United States evince that she cannot be trusted when she represents to the Court that
13 she will not flee, if released."); *United States v. Magana-Guerrero*, 80 F.3d 398, 401 (9th Cir. 1996)
14 ("providing materially false information to a pretrial services officer, whose job it is to conduct
15 investigations for the court, constitutes obstruction of justice for purposes of section 3C1.1, without a
16 specific showing that the falsehood actually obstructed justice"). The Court correctly detained Zhu as a
17 risk of flight and obstruction and he should remain detained.

18 **IV. CONCLUSION**

19 The government respectfully requests the Court deny Zhu's motion for bail review.

20 Dated: April 23, 2024

PHILLIP A. TALBERT
United States Attorney

22 By: /s/ Henry Z. Carbalal III
23 HENRY Z. CARBAJAL III
24 JOSEPH D. BARTON
ARELIS M. CLEMENTE
25 Assistant United States Attorney

EXHIBIT 1

Actions ▾

Passport Details

1 of 3 ►► ►► ►► ►►



Name: ZHU, Jia
Date of Birth:
Sex: Male
Place of Birth: --
Passport #: 2368
Passport Type: --
Document Type: PASSPORT (P)
Document Country: CANADA (CAN)
Issued City: --
Issue Date: --
Expiration Date: 09/20/2023
Document Status: ISSUED
Alias Names (0)

Name	DOB	Type
No records found.		



	Page(s)
To/A	3
Homeland Security Investigations, Foreign Service National Investigator: [REDACTED]	Date November 15, 2023
From/De	Our File/Notre dossier [REDACTED]
Canada Border Services Agency, Intelligence Officer: [REDACTED]	
Subject/Objet	Your File/Votre dossier [REDACTED]
HE, Qiang David [REDACTED] – US Identity	[REDACTED]
ZHU, Jiabei [REDACTED] – Canadian Identity	[REDACTED]

On November 15, 2023, at 13:08hrs, the writer, Regional Intelligence Officer [REDACTED] assigned to the Canada Border Services Agency Ottawa Intelligence Unit received a request for information from the US Homeland Security Investigations – Foreign Service National Investigator: [REDACTED].

Your request for disclosure of CBSA's information regarding Qiang David [REDACTED] and Jiabei ZHU [REDACTED] has been processed.

Subject: HE, Qiang David [REDACTED] (US Identity) no records with CBSA. No travel history to Canada.

Subject: ZHU, Jia Bei [REDACTED] (m) is known to CBSA as a Canadian Citizen UCI#: [REDACTED]

Aliases:

-ZHU JIA, Bei (aka)

-ZHU, Jesse (aka)

-JIA BEI ZHU (certificate)

Travel History:

Last entry to Canada on 2015-09-03.

CAD Passport # [REDACTED] 2368

No results from Outbound query.

EXHIBIT 1

Page 2

Page 1 of 3



Integrated Customs Enforcement System (ICES – Traveller Passage Report):

PROTEC 100 B - ICES - Reporting - (ICES - Traveller Passage Report)

Summary Operational Traveller History Window Help

Traveller Details Results

CRITERIA: 2013/11/14 00:00 to 2023/11/15 15:36

TRAVELLER PASSAGE REPORT

Row 1 of 21

Passage Date/Time	Officer ID	Traveller Name	Date of Birth	Gender	Citizenship	Work Location	Lane	Ref. Type	Occ. Type	Property Code	F OSS Line	Document Type	Document Number	Program Type
2013-12-28 22:57:56 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	56	L	N/A	Y	PASS	298	ABC	
2014-02-18 08:23:07 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	55	L	N/A	Y	PASS	298	ABC	
2014-02-27 00:31:35 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	44	L	N/A	Y	PASS	298	ABC	
2014-02-27 00:31:35 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	56	L	N/A	Y	PASS	298	ABC	
2014-03-31 12:04:57 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	AK03	L	N/A	Y	PASS	298	ABC	
2015-02-15 11:14:24 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	AK05	L	N/A	Y	PASS	298	ABC	
2015-02-21 13:37:11 PT	ZHU, JIA BEI			M	CA	Douglas	TP04	L	N/A	Y	PASS	298	IPIL Highway	
2015-02-27 22:28:28 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	AK17	L	N/A	Y	PASS	298	ABC	
2015-04-05 21:57:40 PT	ZHU, JIA BEI			M	CA	Pacific Highway - Commercial	CP16	L	N/A	Y	PASS	298	IPIL Highway	
2015-04-10 16:41:11 PT	ZHU, JIA BEI			M	CA	Douglas	TP05	L	N/A	Y	PASS	298	IPIL Highway	
2015-04-12 18:33:49 PT	ZHU, JIA BEI			M	CA	Douglas	TP01	L	N/A	Y	PASS	298	IPIL Highway	
2015-04-14 17:23:02 PT	ZHU, JIA BEI			M	CA	Douglas	TP09	L	N/A	Y	PASS	298	IPIL Highway	
2015-04-18 14:28:40 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	AK04	L	N/A	Y	PASS	298	ABC	
2015-04-22 19:18:59 PT	ZHU, JIA BEI			M	CA	Douglas	TP03	L	N/A	Y	PASS	298	IPIL Highway	
2015-04-28 19:13:00 PT	ZHU, JIA BEI			M	CA	Douglas	TP03	L	N/A	Y	PASS	298	IPIL Highway	
2015-05-10 20:32:07 PT	ZHU, JIA BEI			M	CA	Douglas	TP04	L	N/A	Y	EPAS	298	IPIL Highway	
2015-05-23 20:28:28 PT	ZHU, JIA BEI			M	CA	Douglas	TP02	L	N/A	Y	PASS	298	IPIL Highway	
2015-06-02 11:40:15 PT	ZHU, JIA BEI			M	CA	Pacific Highway - Traffic	TP03	L	N/A	Y	PASS	298	IPIL Highway	
2015-06-20 23:22:39 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	AK12	L	N/A	Y	PASS	298	ABC	
2015-08-08 15:38:04 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	12	L	N/A	Y	EPAS	298	IPIL	
2015-09-03 13:24:58 PT	ZHU, JIA BEI			M	CA	Vancouver Int'l Airport - Traffic	AK07	L	N/A	Y	PASS	298	ABC	

Close Print Options... Help... Date Current as of: 2023/11/15 15:36 AT

Authority To Disclose

This information is provided to the Homeland Security Investigations under the authority of Customs Act section 107(8). Customs information may be provided by any person to an official or any other person employed by or representing the government of a foreign state, an international organization established by the governments of states, a community of states, or an institution of any such government or organization, in accordance with an international convention, agreement or other written arrangement between the Government of Canada or an institution of the Government of Canada and the government of the foreign state, the organization, the community or the institution, solely for the purposes set out in that arrangement.

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EXHIBIT 1

Page 3

Page 2 of 3



Please feel free to contact me if you require clarification or additional information.

Regards,

[REDACTED]

Ottawa Regional Intelligence Section

Canada Border Services Agency / Agence des Services frontaliers du Canada
Government of Canada / Gouvernement du Canada

[REDACTED]
[REDACTED].ca

seller

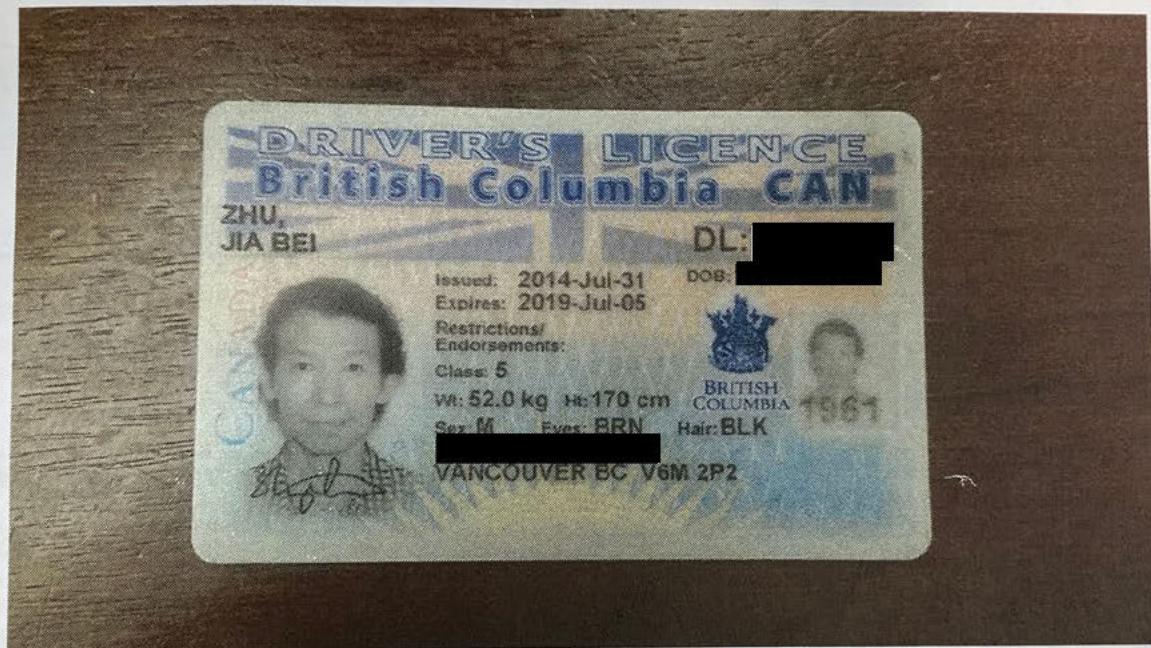


EXHIBIT 1

Page 5

ZHU_00016668

EXHIBIT 2

Establishment Inspection Report

AI DE Diagnostic Co Ltd

Qingdao, Shandong, China

FEI: [REDACTED]
EI Start: 01/25/2016
EI End: 01/28/2016

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SUMMARY

The routine Level 2 inspection of this manufacturer of Class II medical devices was conducted as a Baseline inspection under CP 7382.845, Inspection of Medical Device Manufacturers. The inspection was pre-announced and arranged by DMPTI under the international inspections program.

There was no previous inspection report available for review prior to the current inspection. This was the first inspection of AI DE Diagnostics Co., LTD, Qingdao, Shandong, China.

The current comprehensive QSIT inspection covered the following quality subsystems: Management Controls, Corrective and Preventive Action (CAPA), Design Controls, and Production and Process Controls (P&PC).

Management reported there have been no recalls, no corrections or market withdrawals.

No samples collected, no photographs taken, and no refusals encountered. No objectionable conditions were noted and no FDA 483 was issued. It was discussed with firm management to be in compliance with the Food, Drug & Cosmetic Act and possible penalties were explained.

Unless otherwise noted, [REDACTED] Regulatory Affairs Manager, translated all documents written in Chinese.

ADMINISTRATIVE DATA

Inspected firm: AI DE Diagnostic Co Ltd

Establishment Inspection Report

AI DE Diagnostic Co Ltd

Qingdao, Shandong, China

FEI: [REDACTED]

EI Start: 01/25/2016

EI End: 01/28/2016

Location: 141 Zhuzhou Road
 High-Tech Industrial Park
 Qingdao, Shandong, China 266101

Phone: 0532-88606600

FAX: 0532-88606655

Mailing address: 141 Zhuzhou Road
 High-Tech Industrial Park
 Qingdao Shandong, China 266101

Dates of inspection: 1/25/2016, 1/26/2016, 1/27/2016, 1/28/2016

Days in the facility: 4

Participants: [REDACTED] Investigator

On 01/25/2016, I arrived at the firm and presented credentials to [REDACTED] General Manager. I also displayed my credentials to [REDACTED] Regulatory Affairs Manager, [REDACTED] Manager Assistant, and [REDACTED] Quality Assurance.

Pre-notification and arrangements for this inspection were handled by DMPTI, Medical Device Group.

HISTORY

Ai De Diagnostics Co., LTD (furthermore referred to as "Aide") was founded in November, 2001 as Wei Wei Tech Co., LTD in Qingdao as an exclusively foreign-owned enterprise. According to management, the owners name is Jiabei Zhu.

In 2003, the firm bought 50 acres of land at their present address and first-stage construction of an approximately 13,000 m building started. In September, 2005 the production plant moved into the Zhuzhou Road building. Second-stage construction of an approximately 20,000 m production and office building started in the same location and in October, 2012 the building was put into use. The firm has no subsidiaries.

The Aide production facility in Qingdao is comprised of two buildings: the administrative offices are located on the 3rd floor of one building and production is located on half of the 2nd floor and the entire 3rd floor in the building adjacent to the office building.

Aide is a large-scale integrated Original Equipment Manufacturer (OEM) focusing on research and development, management, production, and sales.

The firm employs 180 employees. Hours of operations were not collected.

Establishment Inspection Report

AI DE Diagnostic Co Ltd

Qingdao, Shandong, China

FEI: [REDACTED]

EI Start: 01/25/2016

EI End: 01/28/2016

The firm's FDA medical device registration is current for 2016.

All official correspondence including FMD-145 should be addressed to:

[REDACTED] General Manager
 Ai De Diagnostics Co., LTD
 No. 141, Zhuzhou Road
 High-tech Industrial Park
 Qingdao, Shandong, China 266101

DISTRIBUTION

The firm is a manufacturer of Class II medical devices. Distributed in the U.S. market are Human Chorionic Gonadotropin (HCG) tests (pregnancy tests) and Luteinizing Hormone (LH) tests (ovulation tests).

Approximately 10% of the Aide products are exported to the U.S. market with 90% being exported to South East Asia, India, United Kingdom, Germany, and Russia. Aide also distributes domestically.

All products manufactured at this facility and distributed in the U.S. are shipped to Aide's only U.S. customer who is as follows:

Diagnostic Automation/Cortez Diagnostics
 23691 Craftsman Rd., Ste. E/F
 Calabasas, CA 91302, USA

Diagnostic Automation (furthermore referred to as DA) performs secondary packaging on the products received from Aide at their facility in California, see **Exhibit 1** for labels of One-Step Tests.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

On 01/25/2016 I arrived at the firm and presented credentials to [REDACTED] General Manager. I also displayed my credentials to [REDACTED] Regulatory Affairs Manager, [REDACTED] Manager Assistant, and [REDACTED] Quality Assurance. [REDACTED] identified [REDACTED] as the most responsible person at the firm due to a language barrier between me and [REDACTED]

An opening meeting ensued with the following management team:

[REDACTED] General Manager

Establishment Inspection Report

AI DE Diagnostic Co Ltd

Qingdao, Shandong, China

FEI: [REDACTED]
 EI Start: 01/25/2016
 EI End: 01/28/2016

[REDACTED] Manager Assistant

[REDACTED] Regulatory Affairs Manager

[REDACTED] Quality Assurance

[REDACTED] **General Manager**, is the most responsible corporate official at the firm according to firm management. [REDACTED] has been with the firm for approximately 1 year. [REDACTED] responsibilities include overseeing operations at the firm and she is the designated management representative according to [REDACTED]. [REDACTED] was present for the opening meeting and did not provide any information included in this report. [REDACTED] reports to Jiabei Zhu, Owner.

[REDACTED] **Regulatory Affairs Manager**, has been with Aide for approximately 1-1/2 years and is responsible for Quality, International Sales, and compliance with laws and regulations. [REDACTED] accompanied me on the inspection, provided the majority of the information contained in this report. He reports to [REDACTED] General Manager.

[REDACTED] **Quality Assurance**, has been with the firm for approximately 1/2 year. Ms. Zhang accompanied me on the inspection and provided some of the information included in this report. She reports to [REDACTED] General Manager.

[REDACTED] **Manager Assistant**, has been with Aide for approximately 1/2 year and is responsible for aiding the manager with day to day tasks. [REDACTED] accompanied me on the inspection and provided assistance to [REDACTED]. She reports to [REDACTED] General Manager.

[REDACTED] **Production Manager**, has been with the firm for approximately 6 years and is responsible for production planning and supervision. [REDACTED] accompanied me on a tour of production. [REDACTED] reports to [REDACTED] General Manager.

See **Attachment 1, (pp 13)** for Aide organizational chart. Aide maintains a website at www.qdaide.com.

FIRM'S TRAINING PROGRAM

The training SOP and training records were reviewed with both found to be complete and adequate with no deficiencies noted.

SCOPE OF INSPECTION

This inspection was a routine inspection of Class II medical devices. The current Baseline QSIT inspection covered the following quality subsystems: Management Controls, Corrective and Preventive Action (CAPA), Design Controls, and Production and Process Controls (P&PC).

Establishment Inspection Report

AI DE Diagnostic Co Ltd

Qingdao, Shandong, China

FEI: [REDACTED]

EI Start: 01/25/2016

EI End: 01/28/2016

MANUFACTURING/DESIGN OPERATIONS

The firm manufactures Class II medical devices. All products are designed, developed, and manufactured at this firm. According to the Quality System Manual, **Exhibit 2**, "Aide is mainly engaged in research, development, production and sales of in vitro diagnostic medical device (IVD), genetic engineering drugs, and bio-engineering drugs, which are sold well all over the world", see **Exhibit 2, (pp 11)**.

The firm holds the following 510(k) for the One Step HCG Pregnancy Test (for both over the counter and prescription):

- K062703 – Substantially Equivalent (SESE)

Management Controls:

During this inspection I reviewed the firm's Quality Management System: Quality System Manual, Document ID: QMS-2014/A, Edition: 03 with no deficiencies noted. [REDACTED] serves in the role of Management Representative for the Quality System.

Internal Audits are conducted yearly with the last audit being performed on May 12-13, 2015.

Management Review meetings with the site management team are held at least one time per year or when necessary. The next meeting is scheduled for March 24, 2016.

Design Controls:

Coverage of the Design Controls system during this inspection focused on the One Step HCG Pregnancy Test and included: batch records, finished device & in-process acceptance activities, DMRs, DHRs, change control procedures, equipment calibration, and training of personnel. All files were found to be adequate with no deficiencies noted.

Corrective and Preventive Actions (CAPA):

Coverage of the CAPA system included complaint files, service & repair records, corrective action reports (CARs), & and non-conformance reports (NCRs) with one deficiency noted concerning complaints.

There were two complaints where investigations were started and these were reviewed during the inspection: 1) on 12/08/2015, Lot # 3-07105, a label for customer was not on the package and the product name was missing. DA employee confirmed that he/she failed to put label on package, left the company and although DA wanted to blame Aide for the problem, I reviewed emails between

Establishment Inspection Report

AI DE Diagnostic Co Ltd

Qingdao, Shandong, China

FEI: [REDACTED]

EI Start: 01/25/2016

EI End: 01/28/2016

Aide and DA that confirmed it was DA's problem; 2) on 12/15/2014, Lot # 5-10034, a large order of 500,000 devices were not the color the customer DA requested so they did not purchase this lot of pregnancy tests from Aide. Since the sale did not go through, Aide stopped their investigation and closed the complaint. I spoke with [REDACTED] about following through on investigations even if a sale is cancelled to determine why the order was not filled correctly, and take action with possible retraining.

[REDACTED] reported the sales force initiates the CAPA & passes on to manufacturing for testing. [REDACTED] also stated approximately 1 or 2 complaints out of approximately 35 are attributed to manufacturing. The department responsible for the CAPA fills out the "reason analysis" on the CAPA form. The responsible department then makes a plan for action and Quality Assurance follows up with the department.

The firm has a five-step plan for handling CAPA and is as follows:

1. Identify
2. Analyze
3. Make plans
4. Implementation & verification of CAPA
5. Close CAPA

Aide had 3 CAPA for 2015: 1) The warehouse audit of product and material stock was not performed due to the responsible employee had left the company and the new employee was not made aware that it needed to be done; 2) The tag had fallen off regarding calibration of measuring equipment which was attached by the calibrator. Calibrator was retrained to double check the tag; 3) Purchasing department bought double-sided tape which needed ISO qualification from the supplier and the supplier changed the name and it became acceptable.

Production and Process Controls:

Coverage of the Production & Process Controls system during this inspection focused on the One Step HCG Pregnancy Test. During a tour of production I observed the following:

- Solution preparation room where solutions for coating & blocking membranes are prepared
- Membrane coating area
- Subsidiary membrane coating area
- Membrane contamination blocking area
- Storage room (membranes cut into strips after retrieved from storage)
- Assembly of parts together into 3 forms:
 - 1. strips for clinical use

Establishment Inspection Report

AI DE Diagnostic Co Ltd

Qingdao, Shandong, China

FEI: [REDACTED]

EI Start: 01/25/2016

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- 2. cassettes for personal use
- 3. pen for home use
- Inner packaging room for strips
 - Put in plastic pouches sometimes 20 together
 - Across from strip packaging area is cassette & pen assembly
- Printing room where lot # & expiration date are printed
- Outer packaging room (plastic pouches put in carton boxes and sealed)
- Cleaning room for brushes, rags, etc.
- Apparatus sterilization room
 - Beakers sterilized in machine and moved to storage
- Quality Control Testing
 - Finished product testing room
 - Raw material testing room
 - Retain sample room
- Apparatus storage room
 - Glassware
 - Beakers
 - Membrane drying racks
- Water preparation room
 - Water is filtered by Reverse Osmosis (RO), multi-media treatment, and water softening to decrease conductivity

All SOPs for each room were observed readily accessible to employees.

Mr. Xu reported all processes are revalidated every 3 years and equipment revalidated every 2 years.

GENERAL DISCUSSION WITH MANAGEMENT

The final discussion was held in a conference room with the following management team:

[REDACTED] Regulatory Affairs Manager
 [REDACTED] Quality Assurance
 [REDACTED] Manager Assistant

I spoke with the management team about following through on investigations even if a sale is cancelled to determine why the order was not filled correctly and to put in place preventive actions. He agreed to correct the practice in the future.

Establishment Inspection Report

AI DE Diagnostic Co Ltd
Qingdao, Shandong, China

FEI: [REDACTED]
EI Start: 01/25/2016
EI End: 01/28/2016

In conclusion, it was discussed with management regarding the firm's responsibilities under the FD&C Act including possible penalties under the Act.

ADDITIONAL INFORMATION

Additional document copies collected during this inspection that were not needed for this report were destroyed by shredding.

EXHIBITS COLLECTED

1. Copy of Quality System Manual (61 pages)
2. Copy of Organization Chart (1 page)

[REDACTED] Investigator

EXHIBIT 3

From: [REDACTED] - Equity Title of Nevada
To: TeamTLT
Subject: WIN 22TKG24336
Date: Friday, May 27, 2022 7:40:44 AM
Attachments: [image001.gif](#)
[image002.jpg](#)

Wire has been posted to your file.

\$837,886.09 Incoming Intl Wire Transfer(s) 208

Transaction Detail for 05/27/2022 as of 07:38:13 AM PDT

PAR Number: [REDACTED]

Swift Ref: [REDACTED]

Date/Time Received: 05/27/2022 05:31:25 AM

Value Date: May 27, 2022

Wire Currency: USD

Wire Amount: 837,886.09

Instructed Amount: USD 837886.09

Sender's Reference: [REDACTED]

Originator: /OSA11014764196008 AI DE DIAGNOSTIC CO., LTD ADD: NO.141 ZHUZHOU RD, LAOSHAN DISTRICT QINGDAO CHN

Originator Bank: SZDBCNBS

Sending Bank: SCBLUS33AXXX STANDARD CHARTERED BANK

Receiving Bank: USBKUS44AIMT U.S. BANK

Beneficiary: [REDACTED] EQUITY TITLE, LLC DBA EQUITY TITLE OF NAVADA ADD: 60 LIVINGSTON AVENUE, ST. PAUL, MINNESOTA 55107 US

Originator To Beneficiary Info: CONT.NO.: [REDACTED] PREPAYMENT 979 SUGAR SPRINGS DRIVE, LAS VEGAS, NV 89110

Charging Option: SHA

Thank you,

[REDACTED] EmailSignature



EXHIBIT 3
Page 1