USP Technology Review: Speedy Breedy

美国药典（USP）技术回顾：

速必得便携式微生物快速检测仪

This report is one of an ongoing series of reports evaluating the capabilities of various screening technologies, performed under USP's established Technology Review program (see Introduction for details).

本报告是一系列正在进行的评估各种筛选技术能力的报告之一，该系列报告源于由美国药典（USP）建立的技术评论项目（详情见简介）。

Table of Contents

目录

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Executive Summary

执行摘要

A technology review was carried out on Speedy Breedy, a portable respirometer manufactured by Bactest. The objective of this review was to determine whether Speedy Breedy can feasibly be used as a first-line screening technology to detect microbial contamination in sterile liquid samples. The performance evaluation involved analysis of three liquid samples (water for injection, artesunate for injection, and oxytocin injection). To mimic potential contamination of samples, some preparations were spiked with bacteria of varying starting concentrations, measured as colony forming units (CFUs). Using standard protocols developed by Bactest, results showed reliable detection of E.coli in sterile water for injection, using the Tryptic Soy Broth (TSB) media vessels, at concentrations as low as 1 CFU and up to 1,000 CFU. E.coli was also detected in sterile water for injection using MacConkey Broth (MCC) media vessels and artesunate for injection and oxytocin injection samples in water for injection using the TSB media vessels, while P. aeruginosa was detected in water for injection, artesunate for injection, and oxytocin injection using Cetrimide Broth (CB) media vessels. All of these bacteria were spiked into the liquid samples at starting concentrations of 20 CFU. Negative controls were run in parallel and confirmatory analysis of samples using an incubator to culture the bacteria and a spectrophotometer to measure optical density at 600nm to avoid false positives and negatives and confirm viability of the inoculated bacteria. A

blinded test was performed with the analyst successfully able to identify contaminated samples and their relative levels of contamination. The field evaluation indicated that inspectors, chemists, microbiologists, and pharmacists with various levels of technical expertise from the regulatory authorities of two countries, India and Zimbabwe, could become either basic, intermediate, or advanced users of the technology within approximately 2 weeks. Speedy Breedy was able to run samples and generate results consistently in uncontrolled field settings, provided a continuous power source was present. Although the instrument has some limitations related to sample throughput and analysis of low volume samples, overall it was able to effectively detect contamination in spiked liquid samples.

本文对由百可测公司生产的便携式呼吸计量仪速必得进行了技术评论。本技术评论的目的是确定速必得是否可以作为检测无菌液体样品中微生物污染的一线筛选技术。性能评估包括对三种液体样品（注射用水、注射用青蒿琥酯和注射用催产素）的分析。为了模拟样品的潜在污染，在一些制剂中加入了不同起始浓度的细菌，作为菌落形成单位（CFU）进行测量。结果表明，使用百可测开发的标准协议，在低至 1CFU 和高达 1000 CFU 的浓度下，均可以可靠的检测出使用胰蛋白酶大豆汤（TSB）培养基容器，在注射用无菌水中检测大肠杆菌是可靠的。使用无菌水注射麦康凯肉汤（MCC）培养皿和使用青蒿琥酯及催产素注射样品用 TSB 培养皿，大肠杆菌都被检测出来。同时使用注射用水、注射用青蒿琥酯和注射用催产素注射西曲明肉汤（CB）培养基均检测到了铜绿假单胞菌。所有这些细菌都以 20 CFU 的初始浓度加入液体样品中。为了避免出现假阳

性和阴性的情况并确认接种细菌的活性，对样本进行了阴性平行实验，使用培养箱培养细菌，并使用分光光度计来测量 600nm 波长的吸光度。分析人员也进行盲法实验，速必得能够成功地识别污染样品及其相对污染程度。现场评估表明，来自印度和津巴布韦两个国家监管部门的不同专业技术水平的检查员、化学家、微生物学家和药剂师，大约仅需 2 周，就可应用这项技术进行初级、中级或高级的操作。速必得能够在不受控制的野外环境中进行取样试验并取得一致的结果，只要有持续的电源即可。尽管仪器在样品处理量和小体积样品分析方面存在一些局限性，但总体而言，它能够有效地检测加标液体样品中的污染情况。

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1. Introduction

Assuring the quality of medicines along all points of the supply chain is vital for promoting positive health outcomes for patients around the world [1]. The importance of medicine quality screening technologies in this endeavor is becoming increasingly recognized [2]. USP has launched the Technology Review program, an initiative guided by a technical expert panel established through the organization's collaborative and volunteer-driven governance and working towards four objectives:

1. Develop standards and guidelines for evaluating medicine quality screening technologies
2. Generate and disseminate tailored information on the capabilities of these technologies through a two-step review process; a lab-based technical performance evaluation and a collaborative field-based utility evaluation.
3. Build the knowledge of key stakeholders to appropriately procure and sustainably utilize screening technologies for the purposes of combating substandard and falsified medicines
4. Foster the development and enhancement of new and emerging screening technologies.

1． 介绍

确保供应链各个环节的药品质量，对世界各地患者的康复起到至关重要的积极效果 [1]。药物质量筛选技术的重要性越来越得到承认[2]。USP 已经启动了技术审查计划，该计划由技术专家小组指导，该专家小组通过志愿性合作机构进

行管理，致力于四个目标：

1. 制定评估药物质量筛选技术的标准和指南；
2. 通过两步审查流程生成并推广有关这些技术的性能的专用资料：基于实验进行的技术性能评估和基于协作现场效果的应用评估；
3. 整合关键利益相关者的信息，恰当的获取并能持续利用筛选技术，从而打击不合格和伪造药品；
4. 促进新兴筛选技术的发展和精进。

This report contributes directly to objectives two, three and four and is the first in what will become an ongoing series evaluating the capabilities of various promising screening technologies.

本报告为目标 2、3 和 4 直接做出了贡献，是将要进行的一系列评估各种有希望的筛选技术性能的第一个报告。

Most of the screening technologies currently in use by regulators, manufacturers and other stakeholders focus on identification of active pharmaceutical ingredients, excipients and other raw materials. Little attention has been paid to the issue of microbial contamination or sterility of liquid samples, a particularly germane problem in low and middle income countries (LMICs) where the security and integrity of the medical product supply chain is difficult to maintain. In addition, the currently available methods and instrument require dedicated clean laboratory space and trained staff to perform the required assessment. To

date, there has been little emphasis on developing methods and instrumentation to perform tests in the field. However, a portable respirometer called Speedy Breedy may present a solution to this concern. Speedy Breedy is a portable respirometer that claims to detect microbial contamination in liquid samples through pressure change measurements over time, which represents microbial respiration[3]. The program, with input from the expert panel and other stakeholders, therefore decided to review Speedy Breedy.

监管机构、制造商和其他利益相关者目前使用的大多数筛选技术都侧重于识别药物活性成分、赋形剂和其他原材料。对液体样品的微生物污染或无菌问题的关注很少，尤其是子中低收入国家（LMIC），在这些国家，医疗产品供应链的安全性和完整性难以保证。另外，目前可用的方法和仪器都需要专门的洁净实验室和经过培训的工作人员来执行所需的评估。到目前为止，很少有人重点关注在户外进行试验的方法和仪器的研发。然而，一种叫速必得的便携式微生物呼吸计量仪可能提供了这一问题的解决方法。速必得是一种便携式微生物呼吸计量仪，通过测量随着时间发生的压力变化来测定液体样品中的微生物污染——这就是微生物呼吸法[3]。因此，在专家小组和其他利益相关者的投入下，决定对速必得进行技术评论。

2. Methodology

2.1. General Information

Table 1 provides general information on Speedy Breedy, namely how it functions, its basic specifications, and the upfront and recurring costs of using the instrument. All data in this section were collected through email exchange,

telephone conversations, and review of the vendor's website between July 2017 and October 2017.

2． 研究方法

2.1 基本信息

表 1 提供了速必得的一般信息，即其功能、基本规格以及使用仪器的前期和经常性成本。本节中的所有数据均来源于在 2017 年 7 月-10 月期间的电子邮件交流、电话沟通和供应商网站审查。

表 1：基本信息

技术	速必得是一种便携式呼吸计量仪，由百可测公司制造。每个仪器有两个腔室，通过测量样品（溶液）中微生物呼吸所产生的压力变化来检测微生物污染情况。
规格	尺寸：13.3 厘米（高），31 厘米（宽），11.2 厘米（深） 重量：2.75kg 电源：交流电源或 12V 直流电源（可提供汽车适配器） 电压：可变（230V/50Hz–120V/60Hz）
相对成本	前期成本 ● 一台机器：8000 美元 经常性成本 ● 8 个培养皿——80 美元

	• 30 包 50 毫升无菌塑料水瓶——40 美元 • 50 毫升无菌注射器 [1]——2 美元 每项测试的大致成本 [2]（不包括样品成本） • 10-15 美元

[1] 非供应商提供
[2] 每项测试的大致费用计算方法是一个培养皿加上一个无菌注射器，再加上一些无菌注射器的损耗。

2.2. Performance Evaluation

2.2 性能评估

Acronyms and Definitions

AS1	Artesunate injection medicine 1
CB	Cetrimide broth (*P. aeruginosa*) culture media pellet
CFU	Colony forming units
MCC	MacConkey broth (*E. coli*) culture media pellet
N	Number of runs
OXY1	Oxytocin injection medicine 1
TSB	Tryptic soy broth media pellet
WFI1	Water for injection brand 1
WFI2	Water for injection brand 2

缩略语和定义

AS1	青蒿琥酯注射液 1
CB	乙酰丙酰胺肉汤（铜绿假单胞菌）培养皿颗粒

CFU	菌落形成单位
MCC	麦康基肉汤（大肠杆菌）培养皿颗粒
N	运行次数
OXY1	催产素注射液 1
TSB	胰蛋白酶大豆肉汤培养皿颗粒
WFI1	注射用水品牌 1
WFI2	注射用水品牌 2

Speedy Breedy Operating Procedure

速必得操作步骤

1. Culture media pellets were allowed to equilibrate to room temperature for 30 minutes.

1.培养基颗粒在室温下放置 30 分钟。

2. Stock controls were prepared at required concentrations for each bacterial cell culture.

2. 每种微生物培养基均按所需浓度制备了备用的对照。

3. For positive control (spiked) samples, the product was spiked with the required concentration of stock control. If necessary, the sample was diluted to obtain sufficient volume of the solution for accurate inoculation of required CFU for the Speedy Breedy and UV-Visible spectrophotometer analysis.

3. 对于阳性对照（加标）样品，将产品加标至所需的制备控制浓度。如有必要，对样品进行稀释，以获得足够体积的溶液为速必得和紫外可见分光光度计的准确分析接种所需的 CFU。

4. The cap was removed from the selected vessel, and 50 mL of the positive control (spiked sample) was introduced into the first vessel through the vessel port using a sterile 50 mL syringe. The cap was then replaced.
4.从所选培养皿中取下盖子，用一个无菌的 50ml 注射器通过容器端口将 50ml 阳性对照品（加标样品）加入第一个培养皿。然后盖上盖子。

5. The cap was removed from the selected vessel and 50 mL of a negative control (unspiked sample) was introduced into the second vessel through the vessel port using a fresh pipette or sterile syringe. The cap was then replaced.
5. 将盖子从所选培养皿中取出，并使用新移液管或无菌注射器通过容器端口将 50 ml 阴性对照品（未加入样品）引入第二个容器。然后盖上盖子。

6. Both vessels were placed into the Speedy Breedy chambers and firmly closed (a click sound confirmed proper closure).
6．两个培养皿都放入速必得腔室中，并牢牢关闭（一声咔哒声说明关闭正确）。

7. The Speedy Breedy analysis was started, using the appropriate test:

7.速必得检测试验开始，使用合适的检测协议：

a. “24h General Contamination Test” for TSB.

b. “E. coli contamination test” for MCC.

c. “P. aeruginosa contamination test” for CB.

a) TSB “24 小时一般污染检测”。

b) MCC“大肠杆菌污染检测”。

c) CB 的“铜绿假单胞菌污染检测”。

8. At the end of a run, the data file was saved and the time of event was recorded.

8．运行结束时，保存数据并记录实验时间。

Time of analysis for Speedy Breedy can exceed 24 hours, and each protocol has its own predetermined run time. All samples were allowed to run for their complete protocol run times. For example, the general contamination test, which uses a TSB media vessel, has a 24-hour run time. See Annex 1 for details about the equipment, consumables, samples, and supplies used during the review.
速必得的检测时长可超过 24 小时，每个协议都有预设的检测运行时间。所有样本都可以在完整的协议运行时间内检测。例如，使用 TSB 培养皿的一般污染检测时间为 24 小时。技术评论期间使用的设备、消耗品、样品和供应品详情见附

件 1。

Confirmatory Analysis

All Speedy Breedy results were confirmed using a shaking incubator and UV-Visible spectrophotometer. After sample preparation, a 50 mL aliquot was transferred into a Speedy Breedy vessel, and an additional 50 mL aliquot was transferred into a tissue culture tube or flask. This flask was then incubated in the shaking incubator at 35 degrees Celsius at 200 RPM. After the appropriate time, growth was determined by visual detection and at an OD of 600 nm using a UV-Visible spectrophotometer. A blank preparation was also run on the UV-Vis.

验证性分析

所有速必得的结果均用振动培养箱和紫外可见分光光度计确认。样品制备后，将 50 ml 等分样品转移到速必得培养皿中，并将另外 50 ml 等分样品转移到组织培养管或烧瓶中。然后将该烧瓶放入振动培养箱中以 35 摄氏度和 200 转/分的速度培养。在适当的时间之后，通过视觉检测和使用 600 纳米的紫外可见分光光度计测定生长。还进行了空白样品检测，使用紫外可见分光光度计测量。

Methodology Limitations

Certain limitations were encountered during this performance review, which were inevitable given the nature of the technology and the objectives of the review. They are identified below: 1. Preparing and diluting low concentration

CFU samples inherently meant that there was the possibility that the CFUs within a given preparation were not fully or reproducibly transferred to the spiked sample. This was observed in certain samples, which did not exhibit a pressure event or turbidity after analysis. This absence of contamination was confirmed through confirmatory analysis and, in situations where this occurred, these data were not used.

技术局限

在本次技术评论中遇到了某些局限性，考虑到该技术的性质和评估的目标，这些局限性是不可避免的。具体确认为如下几点：1.制备和稀释低浓度样品本质上意味着给样品中的微生物可能没有完全或重复地转移到加标样品中。在某些样品中观察到了这一现象，分析后发现这些样品没有出现压力事件或浑浊度。通过验证性分析证实了这种污染情况的缺失，并且在发生了这种情况的数据没有被采用。

2. Not all available media vessels were used for this review; as a result, not all related bacteria were “spiked.” However, the researchers selected two of the most common bacteria found in water, *E. coli* (ATCC 8739) and *P. aeruginosa* (ATCC 9027), which were used for the purposes of the analytical work. The related media vessels—Cetrimide broth for *P. aeruginosa*, MacConkey broth for *E.coli*, and Tryptic Soy Broth for general microbial contamination—were therefore used.

2．这次技术评论并没有使用所有可用的培养基；因此，并不是所有相关细菌都

被“加标”。然而，研究人员选择了水中最常见的两种细菌，大肠杆菌（ATCC 8739）和铜绿假单胞菌（ATCC 9027），进行分析工作。我们使用了与之相关的培养基：铜绿假单胞菌用西曲明肉汤、大肠杆菌用麦康基肉汤，一般微生物污染用胰蛋白酶大豆肉汤。

3. Results 实验结果

3.1 General Information

3.1 基本信息

Data

Bactest can provide the hardware and software in English, simplified Chinese, German, Romanian, and Spanish. Currently, there are no software permissions or instrument locks on Speedy Breedy, and the instrument does not have Internet capabilities; however, if a computer is connected to the Internet, end-of-test notifications can be received However, data can be transferred between devices using the provided SD card or between a device and a PC or laptop using a connection cable provided. There are four types of data files, listed below:

数据

百可测可以提供英文、简体中文、德语、罗马尼亚语和西班牙语的硬件和软件。目前，在速必得上没有软件权限或仪器锁，因此该仪器不能联网；但是，如果计算机联网的话，则可以接收测试结束通知。可以使用提供的 SD 卡或者连接线在一台仪器和电脑或笔记本之间传输数据。数据文件有四种类型，如下所示：

- .SBX are protocol files
- .SBC are calibration files
- .SBR are test results files
- .SB1 and .SB2 are raw data files

- .SBX 是协议文件
- .SBC 是标定文件
- .SBR 是测试结果文件
- .SB1 和.SB2 是原始数据文件

Access, Handling, Maintenance, and Repair 访问、处理、维护和修理

Speedy Breedy is available for procurement and shipment anywhere in the world through Bactest headquarters in the U.K. or the company's distributor network. Repairs currently cannot be performed in the field, so malfunctioning instruments need to be returned for corrective action.

通过英国的百可测总部及其经销商网络，在世界任何地方都可以采购“速必得”。但目前无法在现场进行维修，因此需要退回故障仪器维修。

Durability 耐久性

Speedy Breedy is not waterproof and unshielded, so above normal electromagnetic interference could result in ineffective tests. The instrument is robust but not ruggedized and has not been drop tested. However, provided

temperature, humidity, dust, and vibration changes are not too rapid or severe, the instrument can tolerate fluctuations very well.

速必得不是防水和屏蔽的，因此高于正常值的电磁干扰可能导致无效的测试。该仪器坚固，但未加固，未经跌落测试。但是，如果温度、湿度、灰尘和振动的变化不过快或剧烈，仪器可以很好地承受波动。

Use 使用

Speedy Breedy can analyze liquids, macerated materials, powders, filter membranes, swabs, and bodily fluids. The instrument has media vessels for the following general and specific bacteria and yeasts:

速必得可以分析液体，浸渍材料，粉末，滤膜，拭子和体液。该仪器具有用于以下一般和特殊细菌和酵母菌的培养皿：

Broad spectrum (covers aerobic bacteria and yeasts) •广谱（包括需氧细菌和酵母菌）

General coliforms and *E. coli* •普通大肠杆菌和大肠杆菌

Salmonella spp. 沙门氏菌属

Staphylococcus spp. 葡萄球菌属

Enterococci •肠球菌

Clostridium perfringens •产气荚膜梭菌

Listeria spp. •李斯特菌属

Pseudomonas aeruginosa •铜绿假单胞菌

Campylobacter spp. 弯曲杆菌属

Toxigenic *Vibrio cholera* •产毒霍乱弧菌

Lactic Acid bacteria •乳酸菌

General and wild yeasts •普通和野生酵母

The performance evaluation did not include evaluation of Speedy Breedy's ability to detect anaerobic growth. However, detection of anaerobic growth can be made through the measurement of a pressure differential, irrespective of whether growth is under aerobic or anaerobic conditions. Broad spectrum vessels are recommended to be used, which can be made to be anaerobic. Further details, as well as informational guides, videos, and the latest software, firmware, protocols, and calibration curves can be found on Bactest's website: http://www.speedybreedy.com.

性能评估不包括检测厌氧生长的速必得能力的评估。然而，不管是在好氧还是厌氧条件下生长，都可以通过测量压差来检测厌氧生长。建议使用广谱培养基，可制成厌氧培养基。有关更多详细信息，以及信息指南、视频和最新软件、固件、协议和标定曲线，请访问百可测的网站: http://www.speedybreedy.com。

3.2. Performance Evaluation – Application III: Identification of Contaminants or Impurities

3.2. 性能评估-应用III：污染或杂质的识别

All data below were collected between May 2017 and July 2017. Application III is per the USP Stimuli to the Revision Process: Evaluation of Screening Technologies for Assessing Medicine Quality[4].

以下所有数据收集于 2017 年 5 月到 7 月之间。-应用III是根据美国药典促进修订程序：评估筛选技术，进而评估药品质量[4]。

Speedy Breedy is a portable, precision respirometer, which detects and monitors microbial activity. Detection is observed through pressure transients relating to gaseous exchanges within a 50 mL closed culture vessel as a result of microbial respiration. The instrument uses a motor and stir bar to mix sample solutions, which creates culture conditions that stimulate growth of microbes. This growth facilitates the conversion of gaseous exchange into pressure variances in the headspace of the culture vessel, which are subsequently measured and recorded and can be visualized on a computer using the instrument software. If the variance exceeds the noise threshold defined by a given protocol linked to a particular media pellet measured in pressure change over time (typically more than 0.1 mbar per minute for at least 7 minutes), it is recognized as a pressure event, which signifies contamination.

速必得是一种可靠的精密的便携式呼吸计量仪，用于检测和显示微生物的活动。检测手段是通过在 50ml 封闭培养皿内微生物的呼吸发生的气体交换来检测压力瞬变。该仪器使用一个马达和搅拌棒来混合样品溶液，创造促进微生物生长的培养条件。这个生长有助于将气体交换转化为培养皿顶部空间的压力变

化，测量和记录这些变化之后，可以在计算机上通过软件将这些信息转化为可视化的数据。如果连接中的一个培养皿内随时间的压力变化超过了给定协议的噪波阈值（通常是连续至少 7 分钟超过 0.1 mbar/min），则被视为压力事件，表示样本被污染。

Analysis Conditions 分析条件

Table 2 summarizes the various products that were used as samples and analyzed and highlights the number of runs that were performed under each condition, the media pellet that was used, and whether or not an event was observed for those samples that were spiked.

表 2 总结了用作样品的各种产品，并对其进行了分析，突出了在每种条件下进行的检测次数、使用的培养基以及是否在这些加标样品中检测到事件。

Negative controls were prepared in parallel with all conditions, and no negative control samples had pressure events.

阴性对照组所有条件平行制备，没有阴性对照样品出现压力事件。

Table 2: Condition Details and Presence of an Event

Condition	Product	Media pellet	Bacterial Contaminant	Spiked Conc. (CFU)	N	Pressure Event
A	Water for injection	TSB[3]	*E. coli*	1, 10, 20, 50, 100, 1000	29	Yes
B	Water for injection	MCC	*E. coli*	1, 20, 50	16	Yes
C	Water for injection	CB	*P. aeruginosa*	1, 20, 50	3	Yes
D	Oxytocin injection	CB	*P. aeruginosa*	20	5	Yes
E	Oxytocin injection	TSB	*E. coli*	20	1	Yes
F	Artesunate injection	TSB	*E.coli*	20	1	Yes
G	Artesunate injection	CB	*P. aeruginosa*	20	1	Yes

表 2：条件详情和事件的出现

条件	样品	培养基	细菌污染	样品加标浓度（CFU）	运行次数	压力事件
A	注射用水	TSB[3]	大肠杆菌	1、10、20、50、100、1000	29	是
B	注射用水	MCC	大肠杆菌	1、20、50	16	是
C	注射用水	CB	铜绿假单胞菌	1、20、50	3	是
D	催产素注射液	CB	铜绿假单胞菌	20	5	是
E	催产素注射液	TSB	大肠杆菌	20	1	是
F	青蒿琥酯注射液	TSB	大肠杆菌	20	1	是
G	青蒿琥酯注射液	CB	铜绿假单胞菌	20	1	是

[3] ： See section 2, “Methodology,” for acronyms

[3] ： 见第二部分，“方法论”，缩略语

Reproducibility and Reliability 再现性和可靠性

Table 3 provides statistical data of the samples that were run under condition A.

表 3 提供了在条件 A 下运行的样品的统计数据。

Table 3: Reproducibility, Range, and Reliability of Speedy Breedy under Condition A

Time to Pressure Event (minutes)										
Spiked Conc. (CFU)	**Log_{10} Conc. (CFU)**	**N**	**Min**	**Max**	**Range**	**Mean**	**Stdev**	**% RSD**	**Days[4]**	**Instruments**
1	0	8	714	842	128	792.4	42.2	5.3	4	3
10	1	2	668	720	52	694.0	36.8	5.3	1	2
20	1.3	8	615	842	227	749.4	72.2	9.6	4	3
50	1.7	6	504	688	184	644.7	69.8	10.8	2	3
100	2	3	624	650	26	635.3	13.3	2.1	3	2
1,000	3	2	474	578	104	526.0	73.5	14.0	2	2
Log transformed Pearson's correlation coefficient (all conc.) – R^2								-0.95		

表 3：条件 A 中速必得的再现性、检测范围和可靠性

压力事件检出时间（分钟）										
样品加标浓度（CFU）	对数浓度（CFU）	运行次数	最短时长	最长时长	范围	平均时长	标准偏差	相对标准偏差%	天数[4]	仪器数量
1	0	8	714	842	128	792.4	42.2	5.3	4	3
10	1	2	668	720	52	694.0	36.8	5.3	1	2
20	1.3	8	615	842	227	749.4	72.2	9.6	4	3
50	1.7	6	504	688	184	644.7	69.8	10.8	2	3
100	2	3	624	650	26	635.3	13.3	2.1	3	2
1000	3	2	474	578	104	526.0	73.5	14.0	2	2
对数转换皮尔逊相关系数（所有浓度）–R^2 -0.95										

[4] Represents the number of different days experiments were run on.

[4] 代表实验的运行天数

Runs at all six concentrations gave pressure events on different days and using

different instruments. Three of the spiked concentrations—1, 20, and 50 CFUs—had more than three runs (N), and their time to pressure event ranges and percentage relative standard deviations were 128, 227, and 184 minutes and 5.3 percent, 9.6 percent, and 10.8 percent, respectively. Results for the 20 CFU dataset were also collected by two analysts. The Pearson's correlation coefficient of −0.95 was calculated using the log-transformed concentrations and means as comparator variables.

在所有六种浓度下检测会在不同的天数和使用不同的仪器时产生压力事件。3个加标浓度（1、20 和 50 CFU） 超过 3 次检测（n），其压力事件时间范围和相对标准偏差百分比分别为 128、227 和 184 分钟和 5.3%、9.6%和 10.8%。两位分析师也收集了 20 个 CFU 数据集的结果。皮尔逊相关系数为−0.95，使用对数转换浓度和平均值作为比较变量进行计算。

Figure 1 shows a screenshot of one of the results run under condition A at 20 CFU. The first two gray lines denote the start and end times of the run, while the red line denotes a pressure event. The dark purple and green lines display the pressures in the right and left chambers, respectively, while the faint purple and green lines display the temperatures in the right and left chambers, respectively. The left chamber was spiked, while the right chamber was a negative control. The two peaks at the end of the run represent the optional pasteurization cycle, which can be run after a test to kill non-spore-forming bacteria, such as E.coli.

图 1 显示了在 20CFU 的条件 A 下运行的一个结果的屏幕截图。前两条灰色线表

示运行的开始和结束时间，而红色线表示压力事件。深紫色和绿色线分别显示右腔室和左腔室的压力变化，而淡紫色和绿色线分别显示右腔室和左腔室的温度变化。左腔室是实验组，而右室是阴性对照组。运行结束时的两个峰值代表可选的巴氏杀菌周期，可以在杀死非孢子形成细菌（如大肠杆菌）的测试后运行。

Figure 1: Screenshot of Speedy Breedy Results from an Analysis under Condition A

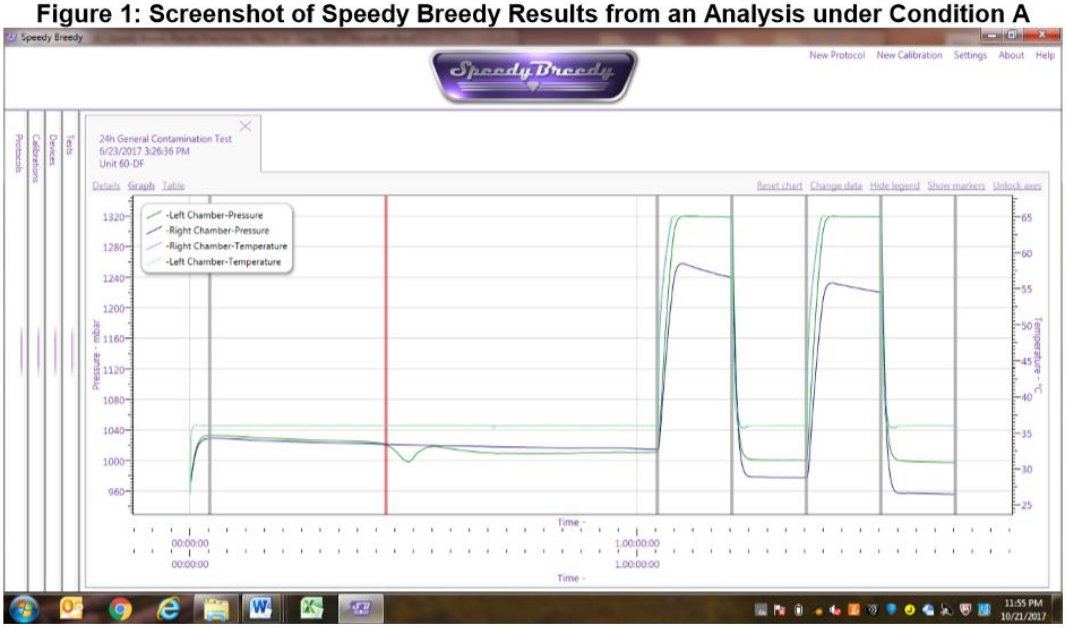

Table 4 provides statistical data of the samples that were run under condition B.

表 4 提供了在条件 B 下运行的样本的统计数据。

Table 4: Reproducibility, Range, and Reliability of Speedy Breedy under Condition B

	Time to Pressure Event (minutes)								
Spiked Conc. (CFU)	**N**	**Min**	**Max**	**Range**	**Mean**	**Stdev**	**RSD**	**Days**	**Instruments**
1	1	932	932	N/A	N/A	N/A	N/A	1	1
20	14	730	1448	718	914.1	178.8	19.6	3	3
50	1	642	642	N/A	N/A	N/A	N/A	1	1

表 4：B 条件下速必得的再现性、检测范围和可靠性

压力事件检出事件（分钟）									
加标浓度（CFU）	运行次数	最短时长	最长时长	范围	平均时长	标准偏差	相对标准偏差	天数	仪器数量
1	1	932	932	N/A	N/A	N/A	N/A	1	1
20	14	730	1448	718	914.1	178.8	19.6	3	3
50	1	642	642	N/A	N/A	N/A	N/A	1	1

A total of 14 runs at 20 CFU gave pressure events on 3 different test days and using all 3 instruments. The range for this dataset was 718, and the percentage relative standard deviation was 19.6 percent. However, this included a possible outlier at 1,448 minutes. The second highest time to pressure event in this dataset was 1,048.

在浓度为 20 CFU 下共运行 14 次，使用 3 个不同的仪器在 3 个不同的试验日内均出现压力事件。该数据集的范围为 718，相对标准偏差百分比为 19.6%。然而，这包括 1448 分钟时可能出现的异常值。在这个数据集中，压力事件的第二高发时间是第 1048 分钟。

Figure 2 shows a screenshot of one of the results run under condition B. The gray lines denote the start and end times of the run, while the red lines denote pressure events. The right chamber contained a sample spiked with E.coli at 50

CFU, while the left chamber contained a sample spiked with E.coli at 1 CFU.

图 2 显示了在条件 B 下运行的一个结果的屏幕截图。灰色线表示运行的开始和结束时间，而红色线表示压力事件。右腔室含有加入 50 CFU 大肠杆菌的样品，而左腔室含有加入 1 CFU 大肠杆菌的样品。

Figure 2: Screenshot of Speedy Breedy Results from an Analysis under Condition B

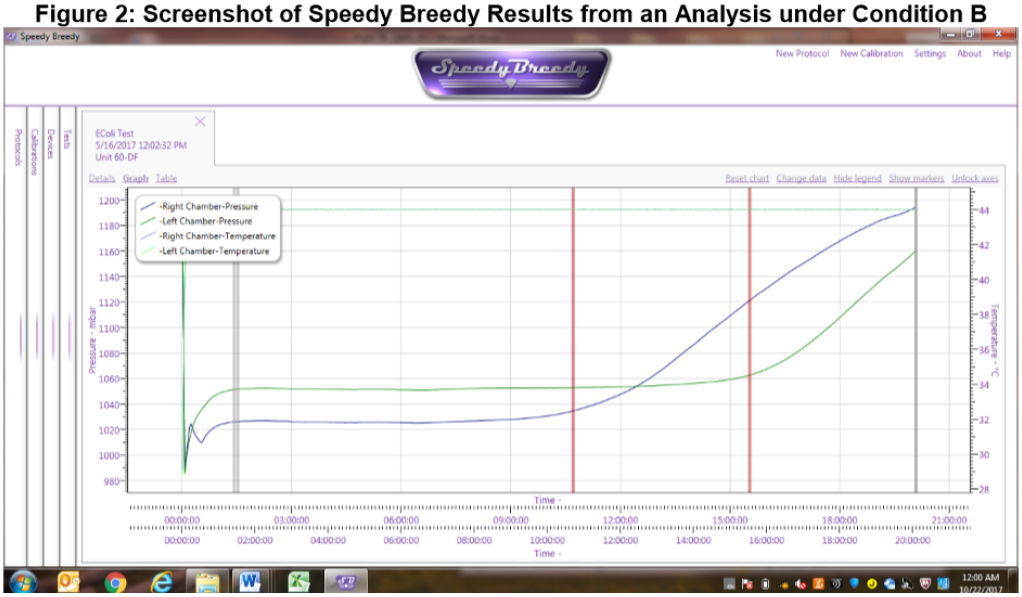

Table 5 provides data of the samples that were run under conditions C, D, E, F, and G

表 5 显示了在条件 C、D、E、F 和 G 下运行的样品的数据。

Table 5: Speedy Breedy Results under Conditions C and D

Condition	Spiked Conc. (CFU)	N	Mean	RSD
C	1	1	1000	N/A
C	20	1	881	N/A
C	50	1	670	N/A
D	1	1	1001	N/A
D	20	3	863	7.0
D	50	1	668	N/A
E	20	1	632	N/A
F	20	1	889	N/A
G	20	1	899	N/A

表 5：C 和 D 条件下的速必得检测结果

条件	加标浓度（CFU）	运行次数	平均时长	相对标准偏差
C	1	1	1000	N/A
C	20	1	881	N/A
C	50	1	670	N/A
D	1	1	1001	N/A
D	20	3	863	7.0
D	50	1	668	N/A
E	20	1	632	N/A
F	20	1	889	N/A
G	20	1	889	N/A

All spiked samples gave pressure events, while none of the negative controls did. However, the time to event is a function of the media being used and as a consequence of the bacteria being screened for. The three runs at 20 CFU under

condition D gave pressure events on 3 different test days and using two different instruments. The range for this dataset was 120 minutes, and the percentage relative standard deviation was 7.0 percent. Results for the 20 CFU dataset under condition D were also collected by two analysts.
所有加标样品均出现压力事件，而阴性对照组均未出现。然而，事件检出的时间是所使用的培养基的一个功能，也是细菌被筛选的结果。在条件 D 下，三次 20 CFU 浓度的运行在 3 个不同的试验日和使用两个不同的仪器时均检出压力事件。这个数据集的压力事件的持续时长是 120 分钟，相对标准偏差的百分比是 7.0%。两位分析师也收集了条件 D 下 20 个 CFU 数据集的结果。

Sensitivity and Specificity 敏感性和特异性

Table 6 and Table 7 provide the true positive and negative rates for the two conditions under which more than three spiked samples were run. Rates were not calculated for conditions where three or less spiked samples were run. True positives were spiked samples that gave pressure events within the protocol run time. True negatives were negative control samples that did not give a pressure even within the protocol run time.
表 6 和表 7 提供了两种情况下超过三个加标样品的真实阳性率和阴性率。未计算三个或三个以下加标样品的条件下的比率。真正的阳性是在协议运行时间内出现压力事件的加标样本。真正的阴性是阴性对照样本，即使在协议运行时间内也不会产生压力事件。

Table 6: True Positive and Negative Rates of Three Concentrations under Condition A

	True Positive		True Negative	
Spiked Conc. (CFUs)	N	Rate	N	Rate
1	8	1.00	2	1.00
20	8	1.00	4	1.00
50	6	1.00	1	1.00

Table 7: True Positive and Negative Rates of One Concentration under Condition B

	True Positive		True Negative	
Spiked Conc. (CFUs)	N	Rate	N	Rate
20	14	0.93	4	1.00

表 6：A 条件下三种浓度的真阳性率和阴性率

	真阳性		**真阴性**	
加标浓度（CFU）	运行次数	比率	运行次数	比率
1	8	1.00	2	1.00
20	8	1.00	4	1.00
50	6	1.00	1	1.00

表 7：B 条件下一种浓度的真实阳性率和阴性率

	真阳性		**真阴性**	
加标浓度	运行次数	比率	运行次数	比率

(CFU)				
20	14	0.93	4	1.00

All three concentrations (1, 20, and 50) analyzed under condition A gave true positive rates of 1.00 and true negative rates of 1.00. Under condition B, 1 of the 14 spiked sample runs gave a false negative, while the true negative rate was 1.00.

在条件 A 下分析的三种浓度（1、20 和 50）的真实阳性率和阴性率分别为 1.00 和 1.00。在条件 B 下，14 次加标样品中的 1 次出现假阴性，而真阴性率为 1.00。

Limit of Detection 检测限

Table 8 provides results for the eight runs that were carried out on spiked samples with starting concentrations of 1 CFU under condition A. Limit of detection was defined as the lowest amount of analyte in a sample that can be detected, but not necessarily quantitated under the state experimental conditions.

表 8 提供了在条件 A 下对初始浓度为 1 CFU 的加标样品进行的 8 次运行的结果。检测限被定义为可检测到的样品中分析物的最低量，但不一定在状态实验下定量[5]。

Table 8: Limit of Detection under Condition A

Spiked Conc. (CFUs)	Time to Pressure Event (mins)	Mean (Time to Pressure Event)	SD	%RSD
1	752			
1	**799**			
1	**842**			
1	**820**	792.4	42.2	5.3
1	**789**	**812.5**	**23.5**	**2.9**
1	714			
1	793			
1	830			

表 8：条件 A 下的检测限

加标浓度（CFU）	压力事件时间（分钟）	平均（压力事件时间）	标准差	相对标准偏差%
1	752	792.4	42.2	5.3
1	799	812.5	23.5	2.9
1	842			
1	820			
1	789			
1	714			
1	793			
1	830			

[5] Definition per USP

[5] 每个 USP 定义

Reproducible events over 4 days using all three instruments were observed when spiking samples with 1 CFU under condition A. The intermediate precision of the eight runs was 5.3 percent. Furthermore, when calculating the precision for the

four runs that took place on the same day on two instruments (data in bold), a precision of 2.9 percent was determined.

在条件 A 下用 1 CFU 加标样品时，使用三种仪器观察到 4 天以上的重复事件。八次测试的中间精度为 5.3%。此外，在计算两台仪器（粗体数据）当天四次运行的精度时，确定了 2.9%的精度。

Table 9: Results of Blinded Test

Time to Pressure Event (mins)	True Concentration	Analyst's Determination
830	1	1
709	20	20
632	100	100
–	Negative control	Negative control

表 9：盲法试验结果

压力事件的时间（分钟）	实际浓度	分析员的决定
830	1	1
709	20	20
632	100	100
-	阴性对照	阴性对照

Table 9 provides the data of a blinded test. After preparation of four samples (a negative control and spiked samples with concentrations of 1, 20, and 100 CFUs, respectively), they were blinded by one analyst and then run by a second analyst. The analyst running the samples was informed that there were four different samples. After running the samples, he evaluated the data and determined the blinded samples he thought corresponded to the four

concentrations. Table 9 indicates that the analyst correctly identified all four samples based on the results obtained with the two Speedy Breedy instruments used.

表 9 提供了盲法测试的数据。制备四份样品后（阴性对照品，添加浓度分别为 1 CFU、20 CFU 和 100 CFU），由一名分析员制备盲法样品，然后由第二名分析员进行检测。运行样本的分析员被告知四个样本是不同的。运行完样品后，他评估了数据，认为与四种浓度不同的盲样是相对应的。表 9 表明，分析员使用的 2 个速必得机器，获得的数据结果正确识别了所有四个样品。

3.3. Field Evaluation

3.3 现场评估

This field evaluation reviewed two major parameters: training requirements and field utility. This work was performed in India and Zimbabwe in August 2017. India and Zimbabwe were selected because they represent two countries with vastly different regulatory environments where screening technologies have not been used extensively in the past but have the potential to be deployed effectively to combat substandard and falsified medicines.

本次现场评估评议了两个主要参数：培训要求和现场实用性。这项评议于 2017 年 8 月在印度和津巴布韦进行。印度和津巴布韦之所以被选中，是因为它们代表了两个监管环境迥异的国家，在过去，筛选技术并没有得到广泛应用，但有可能被有效部署以打击不合格和伪造的药物。

Training Requirements: This first component of the field evaluation involved working with and training local staff in India and Zimbabwe to assess the amount of training required to enable staff to reliably and productively utilize Speedy Breedy in the field. The training involved 5 total days of work, which included 3 days of hands-on and theoretical work followed by 2 days in the field collecting and testing samples. Overall across both countries, 10 staff from the Telangana Drug Control Authority and Medicines Control Authority of Zimbabwe were trained; of these, 6 were laboratory staff (either microbiologists or chemists) and 4 were inspectors. To evaluate the perceived training timeframes for three levels of use of the instrument (basic, intermediate, and advanced), two data sources were used to develop a training timeframe requirements matrix: a survey completed by trainees following the training (Annex 2) as well as the observations of the trainer. Two variables were used to develop the matrix:

培训要求：实地评估的第一个组成部分涉及与印度和津巴布韦当地工作人员合作并培训他们，评估所需的培训内容，使工作人员能够可靠、高效地利用速必得。培训总共需要 5 天个完整的工作日，包括 3 天的实践和理论内容，然后是 2 天的现场采集和测试样品。总的来说，在这两个国家，来自津巴布韦特拉安那药物管制局和药物管制局的 10 名工作人员接受了培训，其中 6 名为实验室工作人员（微生物学家或化学家），4 名为检查员。为了评估仪器三个使用级别（基本、中级和高级）的培训时间框架，使用两个数据源来制定培训时间框架要求矩阵：培训后受训人员完成的调查（附件 2）以及教练的观察。矩阵中有 2

个变量:

1. User experience (prior to training) 用户体验（培训前）:

a. Non-technical experience: A trainee with no prior laboratory experience and no background in one of the physical sciences (e.g., chemistry, biology).
a.无技术经验：没有实验室经验和物理科学（如化学、生物学）背景的受训人员。

b. Technical experience: A trainee with prior experience working in a laboratory and/or a background in one of the physical sciences.
b.有技术经验：具有实验室工作经验和/或物理科学背景的受训人员。

c. Specialized experience: A trainee with theoretical and practical experience utilizing the technology or the technique underpinning the technology.
c.有专业经验：具有理论和实践经验，可应用技术或应用以技术为支撑的相关技巧的受训人员。

2. User type[6] (following training)用户类型（培训后）:

[6] The user type abilities build upon the previous level (e.g., an advanced user can perform the functions of an advanced user as well as a basic and intermediate

user).

[6]用户类型能力建立在前一级的基础上（例如，高级用户可以执行高级用户以及基本和中级用户）。

a. Basic user: A user with the ability to follow a standard operating procedure or work instruction to set up and run the instrument and collect data.

a.基本用户：能够按照标准操作规程或作业指导书来设置和运行仪器并收集数据的用户。

b. Intermediate user: A user with the ability to develop and modify methods and evaluate and interpret results.

b.中级用户：具有开发和修改方法、评估和解释实验结果的能力的用户。

c. Advanced user: A user with the ability to train other staff and perform basic troubleshooting.

c.高级用户：能够培训其他员工并能基本完成故障排除的用户。

Table 10 provides recommended training timeframes for trainees to reach one of three user levels—basic, intermediate, or advanced—based on the performance evaluation, field evaluation, survey given to trainees and local staff, and trainer observations.

表 10 根据绩效评估、现场评估、对受训人员和当地员工进行的调查以及培训师

的观察，为受训人员提供了达到三个基本、中级或高级用户级别的建议培训时间表。

Table 10: Training Timeframe Requirements

User Experience	User Type		
	Basic	***Intermediate***	***Advanced***
Non-technical	Between 1 day and 1 week	1 to 2 weeks	More than 2 weeks
Technical	1 day	Between 1 day and 1 week	1 to 2 weeks
Specialized	1 to 2 hours	2 to 3 days	1 week

表 10：培训时间表要求

用户经验	**用户类型**		
	基本	中级	高级
无技术经验	1 天到 1 周	1 到 2 周	2 周以上
有技术经验	1 天	1 天到 1 周	1 到 2 周
专业技术经验	1 到 2 小时	2 到 3 天	1 周

Field Utility: The second component of the field evaluation involved running samples using Speedy Breedy in field settings and determining the utility of the instrument in these environments. It also included identifying any challenges associated with traveling with Speedy Breedy.

现场实用性：现场评估的第二个组成部分，涉及在现场环境中使用速必得检测样品，并确定仪器在这些环境中的实用性。它还包括验证速必得在外出过程中

受到的所有挑战。

No problems were encountered during routine international air transportation, which included security checks and hand and checked luggage storage on long-haul flights. Travel by vehicle to various sampling sites also did not involve any challenges, and the instrument withstood temperatures between room temperature and approximately 40 degrees Celsius. One current potential limitation of transporting Speedy Breedy and maintaining the instrument is its travel case, which is currently made of cardboard. Perhaps as a result of this, upon inspection of one of the instruments prior to the commencement of training in Hyderabad, a hinge on one of the chamber lids had broken off, disabling this chamber. A spare lid had been included in the case, which was used to easily replace the broken lid with a small screwdriver. Follow-up communication with Bactest confirmed that the manufacturer is in the process of developing a robust travel case, which will include space for consumables. Throughout the course of the field evaluation work, the vendor was contacted numerous times to address concerns and questions. Communication was through email, and responses were received within 24 hours on all occasions. Furthermore, during the field evaluation a new 16-hour E.coli protocol was developed by the manufacturer, shared as an email attachment, and subsequently utilized during one of the training site runs (see Table 10). This protocol was not used as part of the performance evaluation, so data obtained

using this protocol were not used to evaluate the analytical performance of the instrument. However, it presented an opportunity to identify any challenges associated with the deployment of a new protocol in the field. There were no challenges encountered either in uploading the new protocol remotely or subsequently utilizing it for sample analysis.

在日常国际航空运输中没有遇到任何问题，包括安全检查和长途航班的手提行李、托运行李存储。汽车运输到各个采样点也没有任何问题，仪器能承受室温到大约 40 摄氏度之间的温度。目前运输和维护速必得仪器的一个潜在限制是其包装箱，目前由纸板制成。可能因为这个原因，在开始在海得拉巴的培训之前，对仪器进行检查后，其中一个仪器腔室盖子上的铰链断开，使该舱盖失能。箱子里有备用盖子，用一把小螺丝刀很容易地把坏了的盖子换掉。后续与百可测沟通证实，制造商正在开发一个更牢固的旅行箱，其中设置消耗品空间。在现场评估工作的整个过程中，多次通过电子邮件联系供应商以解决问题，所有情况下都在 24 小时内收到了回复。此外，在现场评估期间，制造商开发了一个新的 16 小时大肠杆菌协议，作为电子邮件附件共享，随后在一个培训站点运行期间使用（见表 10）。这个协议并没有作为性能评估的一部分，因此使用本协议获得的数据不用于评估分析该仪器性能。但是，它提供了一个机会，来确认在现场部署一个新协议可能会面临的问题。无论是远程上传新协议，还是随后将其用于样本分析，都没有遇到任何问题。

Because there was no guarantee that contaminated samples would be found during the field work, some spiked samples, negative control samples, and

regular samples were run at the training sites to demonstrate the difference between pressure events and non-events to trainees. Table 11 provides the details of these runs. Apart from the first runs in each country, all samples were prepared and run by the trainees.

由于无法保证在现场实验期间会发现受污染的样品，因此在培训现场测试了一些加标样品、阴性对照样品和常规样品，来给受训人员示范压力事件和无事件的差别。表 11 提供了这些实验的详细信息。除了在每个国家的首次运行外，所有样品都是由受训者准备和测试的。

Table 11: Spiked Samples Run at Training Facility in India and Zimbabwe

Run (Cbr[7])	Training Site	Sample	Spiked with	Protocol	Result
T1 (1)	India	Gentamicin inj.[8]	N/A	24h GC	No event
T1 (2)	India	Sterile WFI	N/A	24h GC	No event
T2 (1)	India	Ringer lactate solution	N/A	24h GC	No event
T2 (2)	India	Sterile WFI	*S. aureus*	24h GC	Event
T3 (1)	India	Milli-Q water	*E. coli*	16h EC	Event
T3 (2)	India	Milli-Q water	N/A	16h EC	No event
T4 (1)	India	Sterile WFI	*E. coli*	24h GC	Event
T4 (2)	India	Sterile WFI	N/A	24h GC	Event
T5 (1)	India	Sterile WFI	N/A	24h GC	Event
T5 (2)	India	Sterile WFI	N/A	24h GC	No event
T6 (1)	Zimbabwe	Sterile NaCl	N/A	24h GC	No event
T6 (2)	Zimbabwe	Sterile NaCl	N/A	24h GC	No event
T7 (1)	Zimbabwe	Sterile NaCl	N/A	24h GC	No event
T7 (2)	Zimbabwe	Sterile NaCl	N/A	24h GC	No event
T8 (1)	Zimbabwe	Tap water	N/A	24h GC	Event
T8 (2)	Zimbabwe	Bottle water	N/A	24h GC	Event
T9 (1)	Zimbabwe	Tap water	N/A	24h GC	Event
T9 (2)	Zimbabwe	Bottle water	N/A	24h GC	Event
T10 (1)	Zimbabwe	Artesunate injection[8]	N/A	24h GC	Event
T10 (2)	Zimbabwe	Artesunate injection[8]	N/A	24h GC	No event

表 11：在印度和津巴布韦培训机构进行的加标样本

运行（腔室[7]）	培训现场	样本	加标样本	协议	结果

T1（1）	印度	庆大霉素注射液[8]	N/A	24 小时 GC	无事件
T1（2）	印度	无菌注射用水	N/A	24 小时 GC	无事件
T2（1）	印度	乳酸溶液	N/A	24 小时 GC	无事件
T2（2）	印度	无菌注射用水	金黄色葡萄球菌	24 小时 GC	压力事件
T3（1）	印度	Milli-Q 水	大肠杆菌	24 小时 EC	压力事件
T3（2）	印度	Milli-Q 水	N/A	24 小时 EC	无事件
T4（1）	印度	无菌注射用水	大肠杆菌	24 小时 GC	压力事件
T4（2）	印度	无菌注射用水	N/A	24 小时 GC	压力事件
T5（1）	印度	无菌注射用水	N/A	24 小时 GC	压力事件
T5（2）	印度	无菌注射用水	N/A	24 小时 GC	无事件
T6（1）	津巴布韦	无菌 NaCl	N/A	24 小时 GC	无事件
T6（2）	津巴布韦	无菌 NaCl	N/A	24 小时 GC	无事件
T7（1）	津巴布韦	无菌 NaCl	N/A	24 小时 GC	无事件
T7（2）	津巴布韦	无菌 NaCl	N/A	24 小时 GC	无事件
T8（1）	津巴布韦	自来水	N/A	24 小时 GC	压力事件

T8（2）	津巴布韦	瓶装水	N/A	24 小时 GC	压力事件
T9（1）	津巴布韦	自来水	N/A	24 小时 GC	压力事件
T9（2）	津巴布韦	瓶装水	N/A	24 小时 GC	压力事件
T10（1）	津巴布韦	青蒿琥酯注射液[8]	N/A	24 小时 GC	压力事件
T10（2）	津巴布韦	青蒿琥酯注射液[8]	N/A	24 小时 GC	无事件

[7] CBR=腔室

[8] 由于样品单位体积小，这些样品用无菌注射用水（印度）或无菌氯化钠（津巴布韦）填充至 50 毫升，以便进行分析。

Although several unexpected results were obtained during these runs, notably runs T2(2), T4(2), and T5(1), no results for either the training site runs or field evaluations were used for the performance evaluation data analysis, as conditions for these runs were deliberately uncontrolled. The purpose of these runs was to determine whether trainees could operate the instrument and whether the instrument could operate in true field settings.

虽然在这些实验过程中获得了一些意想不到的结果，特别是实验组 T（2）、T4（2）和 T5（1），但由于这些运行的条件是不受控制的，因此没有将培训现场实验或现场评估的结果用于性能评估数据分析。这些实验的目的是确定受训人员是否可以操作仪器，以及仪器是否可以在真正的现场情境中操作。

In follow-up to the trainings, Speedy Breedy units were taken to pharmacies and rural retail outlets, as well as a parenteral manufacturer where samples were run overnight due to protocol run times. Table 11 provides details of these runs. None of these samples were spiked.

在培训的后续工作中，速必得机器被带到药店和农村零售店，以及一个注射用产品生产商，在那里，由于协议运行时长的原因，样品检测隔夜。表 11 提供了这些实验的详细信息。这些样品中没有一个是加标的。

Table 12: Samples Run at Field Sites in India and Zimbabwe

Run (Cbr)	Training Site	Location	Sample	Protocol	Result
F1 (1)	India	Rural health outpost	Metronidazole inj.[8]	24h GC	No event
F1 (2)	India	Rural health outpost	Ciprofloxacin inj.[8]	24h GC	No event
F2 (1)	India	Parenteral Mfr	Sterile NaCl	24h GC	Event
F2 (2)	India	Parenteral Mfr	Purified water	24h GC	Event
F3 (1)	Zimbabwe	Retail Pharmacy	Metronidazole inj.[8]	24h GC	No event
F3 (2)	Zimbabwe	Retail Pharmacy	Metronidazole inj.[8]	24h GC	No event

表 12：在印度和津巴布韦的实地取样

运行（腔室）	培训站点	位置	样本	协议	结果
F1（1）	印度	农村卫生哨站	甲硝唑注射液[8]	24 小时 GC	无事件
F1（2）	印度	农村卫生哨站	环丙沙星注射液[8]	24 小时 GC	无事件
F2（1）	印度	Parenteral Mfr	无菌 NaCl	24 小时 GC	压力事件

F2（2）	印度	Parenteral Mfr	纯化水	24 小时 GC	压力事件
F3（1）	津巴布韦	零售药店	甲硝唑注射液[8]	24 小时 GC	无事件
F3（2）	津巴布韦	零售药房	甲硝唑注射液[8]	24 小时 GC	无事件

Although no malfunctions were encountered as a result of the instruments, several external factors led to some invalid tests, which were subsequently repeated. These factors are listed below:

尽管仪器没有出现任何故障，但一些外部因素导致出现了几个无效的测试结果，随后重做了这些测试。这些因素如下：

At one facility, a power interruption early during a run meant the analysis needed to be repeated the next day.

在一家机构，检测期间电源提早中断，意味着需要在第二天重新运行。

At another facility, a ciprofloxacin injection was analyzed. Review of the results the next day showed a foamy solution with what appeared to be some precipitate. A pressure change had taken place early during the run but, as the system had not stabilized, an event was not recorded. The 24-hour general contamination test protocol had been run using TSB.

在另一家机构，对环丙沙星注射液进行了分析。第二天对结果的回顾显示，有泡沫的溶液似乎有一些沉淀物。压力变化在运行初期发生，但由于系统没有稳定，因此没有记录压力事件。使用 TSB 培养基运行了 24 小时一般污染检测协议。

4. Review and Conclusions 回顾与结论

4.1. Performance Evaluation 性能评价

Conditions A and B had 29 and 16 data points, respectively, which have been used to draw general conclusions about the functionality of Speedy Breedy as a screening technology. As mentioned earlier, these two conditions were chosen because the authors felt water for injection presented an excellent initial case study sample considering its breadth of use globally. Furthermore, E.coli is one of the common microorganisms found in contaminated water. However, data were collected for five other conditions, including two additional samples, an additional media vessel, and bacteria (see Table 1). Additional protocols and media vessels exist for other common bacteria, enabling targeted contamination detection based on the previous experience of prospective users.

条件 A 和条件 B 分别有 29 和 16 个数据点，根据这些数据点，分析得到了速必得作为一种筛选技术的功能性方面的结论。如前所述，考虑到其在全球的广泛使用，选择这两个条件是因为作者认为注射用水是一个极好的初始案例研究样

本。此外，大肠杆菌是水污染中常见的微生物之一。然而，收集了 5 种其他条件的数据，包括两个额外的样品、一种额外的培养基和细菌（见表 1）。针对其他常见细菌，供应商也有其他协议和培养基，可根据潜在用户的以往经验进行有针对性的污染检测。

Condition A results (see Table 2) included samples with six different starting concentrations of bacteria, as low as 1 CFU and as high as 1,000 CFU. Three different instruments were used to collect data over the course of 16 days of work. All 29 spiked samples run under condition A gave pressure events reflected in the 1.00 true positive rates seen in Table 6. Furthermore, none of the negative controls gave pressure events leading to true negative rates of 1.00, as seen in Table 5, implying no false positive results. Although samples with starting concentrations of 10, 100, and 1,000 CFU were excluded from the true positive and true negative calculations because only two, three, and two runs were conducted for these concentrations, respectively, their true positive and negative rates were also 1.00. Table 8 also shows that the instrument could reliably detect contamination down to a starting concentration of 1 CFU. Although the %RSD was quite low for the eight runs (5.3 percent) and even lower for the three runs taking place on the same day (2.9 percent), putting the results into the context of the instrument's possible field use, the important point is that all eight runs resulted in a pressure event.

条件 A 的实验结果（见表 2）包括六种不同细菌起始浓度的样品，低至 1

CFU，高达 1000 CFU。在 16 天的实验过程中，使用了三台不同的仪器来收集数据。所有 29 个加标样品均在条件 A 下运行，得出了表 6 中 1.00 真阳性率所反映的压力事件。此外，如表 5 所示，阴性对照组均未出现压力事件，真阴性率为 1.00，这意味着没有假阳性结果。尽管起始浓度为 10、100 和 1000 CFU 的样品被排除在真正的阴阳性比率之外，因为对这些浓度分别进行了两次、三次和两次测试，它们的真正阴性率和阳性率也为 1.00。表 8 还表明，该仪器能够可靠地检测到初始浓度仅为 1 CFU 污染物。尽管 8 次检测的相对标准差百分比很低（5.3%），而同一天内进行的 3 次检测的相对标准差百分比甚至更低（2.9%），但考虑到可能的仪器现场使用范围，最重要的是所有 8 次检测都检测到了压力事件。

Condition B results (see Table 4) included samples with three different starting concentrations of bacteria; 1, 20, and 50 CFU. Only one run was conducted for starting concentrations of 1 and 50 CFU. However, three different instruments were used to collect data over the course of 3 days of work at the starting concentration of 20 CFU. Under condition B, 13 of the 14 runs gave pressure events, reflecting a true positive rate of 0.93. None of the negative controls gave pressure events. This analysis indicates that Speedy Breedy seems to reliably and reproducibly detect various level of E.coli contamination in water for injection using the MCC and TSB media vessels.

条件 B 结果（见表 4）包括三种不同细菌起始浓度的样品：1、20 和 50 CFU。仅对 1 和 50 CFU 的起始浓度进行了一次检测。然而，使用三台仪器在 3 天里

检测了起始浓度均为 20 CFU 的样本，并收集数据。在条件 B 下，14 次检测中有 13 次出现压力事件，真阳性率为 0.93。阴性对照组均未出现压力事件。这项分析表明，速必得似乎可以可靠和重复地检测注射用水中不同浓度的大肠杆菌污染，使用的是 MCC 和 TSB 两种培养基。

A review of the quantitative capabilities of the instrument was not performed, as any detectable contamination in a sterile product means it is no longer sterile. However, the Pearson's correlation coefficient ($R^{2)}$ was calculated using the data collected under condition A (see Table 3) and gave an R2 of −0.95. These data indicate that there is a linear inverse relationship between the log-transformed amount of contamination and the time to detection. These data, coupled with the low %RSDs seen for those samples run at least six times under condition A, provide some basis for the possibility that semi-quantitative protocols could be developed in situations where knowledge of the concentration of contamination is needed.

没有对仪器的定量能力进行审查，因为在任何无菌产品中检测到污染都意味着它不再无菌。然而，皮尔逊相关系数（R^2）是使用在条件 A 下收集的数据计算得出的（见表 3），结果为−0.95。这些数据表明，污染的对数转换量与检测时间呈逆线性关系。这些数据加上在条件 A 下检测至少六次样品得出的相对标准差的低百分比，在需要检测污染浓度的时候，为制定半定量协议的可能性提供了一些基础。

Of the four remaining conditions, under which data were collected, only the 20 CFU starting concentration for condition D had more than one result. However, each of the spiked samples for conditions C, E, F, and G, including those of condition D, gave a pressure event, and no pressure event was observed for any of the negative controls; this indicates that at least two additional sample matrices do not seem to inhibit the ability of Speedy Breedy to detect contamination.

其余四个条件中，所有数据均做记录。只有条件 D 起始浓度为 20CFU 有一个以上的检测结果。然而，条件 c、e、f 和 g 的每一个加标样品，包括条件 d，都检测到压力事件，并且没有观察到任何阴性对照的压力事件；这表明至少两个额外的样品矩阵似乎没有抑制速必得检测污染的能力。

Lastly, to mimic what a user would encounter in the field, one analyst was given four blinded samples to analyze (see Table 9); three of these were contaminated (at starting concentrations of 1, 20, and 50 CFU), and one was not. Using the results, the analyst was able not only to identify the three contaminated samples but also to correctly identify their relative concentrations based on their times to detection.

最后，为了模拟用户在现场遇到的情况，一名分析师对四个盲样进行了分析（见表 9）；其中三个样品受到污染（初始浓度为 1、20 和 50 CFU），另一个没有受到污染。利用这些结果，分析人员不仅能够识别出三种受污染的样品，而且能够根据检测的时长确定它们的相对浓度。

4.2 Field Evaluation

4.2 现场评估

Based on feedback from trainees and the ongoing observations of the trainer, the training required to become a basic, intermediate or advanced user of the instrument was manageable. More specifically, a variety of staff with both technical and non-technical backgrounds can become either basic, intermediate or advanced users within approximately 2 weeks of training. The software was easy to download onto a PC and intuitive to use. Additional work by Bactest could assess the feasibility of developing a smartphone application to enhance the field utility of the instrument. Furthermore, as advanced users continue to refine their deployment of Speedy Breedy, and in environments where the supply chain is a particular challenge, users can develop their own media using empty aerobic or anaerobic vessels. Protocols include the option of a pasteurization cycle, which increases the heat of the vessels to 65 degrees Celsius for several hours post-run, ostensibly killing any non-spore-forming bacteria within a sample, aiding in the disposal of the media. Particularly in field settings where biological waste containers may not be available, this is a very useful feature. It is important to note, however, that the pasteurization cycle does not kill spore-forming bacteria or extreme thermophiles. Vessels must still be disposed of according to local regulations.

根据受训者的反馈和教练的持续观察，培训仪器的基本、中级或高级用户所需的训练是可控的。更具体地说，具有技术和非技术背景的各种员工可以在大约 2 周的培训时间内成为基本用户、中级用户或高级用户。这个软件很容易下载到电脑上，使用起来很直观。百可测可以额外开发安装在智能手机上面的应用程序以增强仪器的现场实用性。此外，随着高级用户不断改进其速必得的部署，在供应链面临特殊挑战的环境中，用户可以开发自己的培养基，使用百可测空的有氧或无氧培养皿。协议包括选择巴氏杀菌，即在运行后将培养皿的温度提高到 65 摄氏度，持续几小时，表面上杀死样品中的所有非孢子形成细菌，以助于培养基的后续处理。特别是在可能没有生物废弃物容器的现场环境中，这是一个非常有用的特性。然而，需要注意的是，巴氏杀菌循环不会杀死孢子形成细菌或极端嗜热菌。培养皿仍必须按照当地法规处理。

Although Bactest has 43 distributors globally, currently there are only 2 in low- or low-middle income countries. This could present problems particularly in countries where shipping and import delays are common. However, media vessels and an instrument were shipped from Bactest headquarters to Zimbabwe in preparation for the field evaluation and arrived within a week of the order being confirmed. Furthermore, the technical support provided by Bactest during the field evaluation was prompt and efficient.

尽管百可测在全球拥有 43 家经销商，但目前在低收入或中低收入国家只有 2 家。这可能会出现问题，尤其是在航运和进口延误普遍的国家。但是，培养皿和一台仪器已从巴克斯特总部运往津巴布韦，为现场评估做准备，并在订单确

认后一周内抵达。此外，百可测在现场评估过程中提供的技术支持是及时有效的。

Some challenges were encountered during the field evaluation. The existing carry case is made of cardboard and not particularly sturdy, which could limit the lifespan of the instrument if it is being used in challenging environments. Moving forward, a pelican case would help preserve the integrity of the instrument and may perhaps have prevented one of the chamber lids from breaking. Additionally, at this stage, media vessels do not have a mark identifying where 50 mL of solution is. This would be particularly useful in situations where graduated syringes are not available or samples are transferred directly into vessels. Related to this, vessels are currently only available in 50 mL volumes. For small volume samples, this presents both an opportunity and a challenge. It provides the potential for pooling samples, for example combining 10 5-mL injectable samples to increase throughput in each chamber. If an event is detected, then the samples can be broken into smaller sample sets to ultimately identify the contaminated product. However, decreasing the number of samples being run decreases the total volume in a vessel for a run, which currently needs to be 50 mL. Researching the possibility of developing smaller volume vessels would allow users to customize their systems. For example, hospital pharmacies working predominantly with 1-L sterile saline bags would have no problem using the current 50mL vessels. However, inspectors working

in rural areas, where the samples in a health outlet are limited and generally small, volume injectables could use smaller volume vessels rather than risking a false positive by filling the sample to volume with bottled water.
实地评估期间遇到了一些问题。现有的手提箱由硬纸板制成，不够坚固，如果在恶劣的环境中使用，可能会限制仪器的使用寿命。进一步，合适的箱子将有助于保持仪器的完整性，可能也会防止其中一个腔室盖子破裂。此外，在此阶段，培养皿没有标识 50 毫升溶液的位置。这在没有刻度注射器或样品直接转移到容器中的情况下特别有用。与此相关的是，目前只有 50 毫升容量的培养皿可用。对于小批量样品，这既是一个机会，也是一个挑战。它提供了收集样本的潜力，例如结合 10 个 5ml 可注射样本以增加每个腔室的处理量。如果检测到一个事件，那么可以将样本分成更小的样本集，以最终识别受污染的产品。但是，减少正在运行的样品数量会减少一个运行培养皿中的总体积，而目前培养皿内需要 50 毫升样本。研究开发更小体积的培养皿将给用户自定义其系统的可能性。例如，医院药房主要使用 1 升装无菌生理盐水袋，使用目前的 50 毫升培养皿没有问题。然而，在农村地区工作的检查员，供给卫生检测的样品有限，且通常体积小，则可以使用体积较小的培养皿，而不是冒着用瓶装水将样品填充至一定体积的假阳性风险。

Although unavoidable, the run time of protocols does limit the effectiveness of the instrument in true field settings where reliable power may not exist even though analysis times are significantly shorter than current confirmatory sterility testing procedures. This was reiterated by several trainees, one of whom

suggested “a rechargeable battery or solar power source” as a solution. The current configuration of only two chambers also limits the sample throughput of the instrument. However, sample pooling is one possible solution to mitigate this limitation, and increasing the number of chambers would commensurately increase the footprint of the instrument, which currently is small, light, and easy to transport.

尽管不可避免，但协议的运行时间确实限制了仪器在真实现场环境中的有效性，尽管分析时长明显短于当前的验证性无菌检测程序，但在这种环境中可能不存在可靠的电源。一些受训者反复提到了这一点，其中一人建议采用“可充电电池或太阳能电源”作为解决方案。目前只有两个腔室的配置也限制了仪器的样本吞吐量。然而，样本池是缓解这一限制的一种可能的解决方案。增加腔室的数量将相应地增加仪器的占地面积，目前该仪器体积小、重量轻且易于运输。

References

[1] PQM, Annual Performance Report FY 2017, Promoting the Quality of Medicines program, Washington, D.C., 2017.

[2] IOM, Countering the Problem of Falsified and Substandard Drugs, Institute of Medicine (now the National Academies of Sciences, Engineering, Medicine), Washington, D.C., 2013.

[3] Bactest, “How Speedy Breedy Works,” 2014. [Online]. Available: http://www.speedybreedy.com/introduction/how-speedy-breedy-works/. [Accessed 29 November 2017].

[4] USP Review of Surveillance and Screening Technology for the Quality Assurance of Medicines Expert Panel, “Stimuli to the Revision Process: Evaluation of Screening Technologies for Assessing Medicine Quality (USP PF 43 (5)),” September 2017. [Online]. Available: http://www.usppf.com/pf/pub/index.html. [Accessed 29 November 2017].

参考文献

[1] PQM，2017 财年年度绩效报告，促进药物质量计划，华盛顿特区，2017 年。

[2] 国际移民组织，《应对伪造和不合格药物问题》，医学研究所（现为国家科学院、工程院、医学院），华盛顿特区，2013 年。

[3] Bactest，“速必得如何运行”，2014 年。[在线]。网址：http://www.speedy

breedy.com/introduction/how speedybreey works/。[访问日期：2017 年 11 月 29 日]。

[4] 美国药典药品质量保证监督筛选技术审查专家组，“修订过程的刺激因素：评价药品质量的筛选技术”（美国药典 PF 43（5）），”2017 年 9 月。[在线]。网址：http://www.usppf.com/pf/pub/index.html。[访问日期：2017 年 11 月 29 日]。

Annex 1. Equipment, Consumables, Samples and Supplies Used during Performance Evaluation

Item	Manufacturer	Expiry Date	Other details
Speedy Breedy – unit 1	Bactest	N/A	Serial No: 40-D8-55-00-60-E4
Speedy Breedy – unit 2	Bactest	N/A	Serial No: 40-D8-55-00-60-EB
Speedy Breedy – unit 3	Bactest	N/A	Serial No: 40-D8-55-00-60-DF
CB media vessel	Bactest	12 October 2017	Part No: BAC023-1
MCC media vessel	Bactest	11 December 2017	Part No: BAC022-1
TSB media vessel	Bactest	12 October 2017	Part No: BAC021-1
Sterilized water for injection (WFI 1)	Marck Bioscience Ltd.	March 2018	Batch No: 2T545054
Sterilized water for injection (WFI 2)	Nirma Ltd.	November 2017	Batch No: 2501112
Glunate 60 mg Artesunate for injection (AS 1)	Guilin Pharmaceutical Co. Ltd.	23 March 2018	Batch: LA150556
Syntocinon 10 IU/UI (OXY 1)	Novartis	October 2020	Batch No: SO634
Analytical balance	Mettler Toledo	N/A	Model: ML3001E
Autoclave	All American	N/A	Model:75X
Fridge	Thermo Scientific	N/A	Model: Revco
Incubating shaker	Eppendorf	N/A	Model: New Brunswick
Incubator	Lovibond	N/A	Model: TC175S
UV-Vis spectrophotometer	Merck	N/A	Model: Pharo 300
Escherichia coli	ATCC (8739)	30 April 2018	Batch No: 61726100
Pseduomonas aeruginosa	ATCC (9027)	31 July 2020	Batch No: 61461178

附件 1 性能评估期间使用的设备、消耗品、样品和供应品

物品	制造商	有效期	其他详细信息
速必得-1 号机组	BACTEST	N/A	序列号：40-D8-55-00-60-E4
速必得-2 号机组	BACTEST	N/A	序列号：40-D8-55-00-60-EB
速必得-3 号机组	BACTEST	N/A	序列号：40-D8-55-00-60-DF
CB 培养基	BACTEST	2017 年 12 月 11 日	零件号：BAC023-1
MCC 培养基	BACTEST	2017 年 10 月 12 日	零件号：BAC022-1
TSB 培养基	BACTEST	2017 年 10 月 12 日	零件号：BAC021-1
注射用灭菌水	Marck Bioscience	2018 年 3 月	批号：2T545054

（WFI 1）	Ltd.		
注射用灭菌水（WFI 2）	Nirma Ltd.	2017 年 11 月	批号：2501112
注射用青蒿琥酯 60 mg（AS 1）	桂林医药股份有限公司	2018 年 3 月 23 日	批号：LA150556
催产素 10 IU/UI（OXY 1）	诺华	2020 年 10 月	批号：SO634
分析天平	梅特勒-托莱多	N/A	型号：ML3001E
高压灭菌器	全美国	N/A	型号：75X
冰箱	热科学	N/A	型号：Revco
摇床	Eppendorf	N/A	型号：New Brunswick
培养箱	Lovibond	N/A	型号：TC175S
紫外可见分光光度计	Merck	N/A	型号：Pharo 300
大肠杆菌	ATCC（8739）	2018 年 4 月 30 日	批号：61726100
铜绿假单胞菌	ATCC（9027）	2020 年 7 月 31 日	批号：61461178

Annex 2. TR Field Evaluation Training Survey

Q1 - Which of the following roles best represents your current position?

#	Answer	%	Count
1	Analyst / Chemist / Microbiologist	66.67%	6
2	Inspector	33.33%	3
3	Customs officer	0.00%	0
4	Other. Please specify	0.00%	0
	Total	100%	9

附件 2 TR 现场评估培训调查

问题 1-以下哪一个角色最能代表你目前的职位?

#	回答	%	计数
1	分析员/化学家/微生物学家	66.67%	6
2	检查员	33.33%	3
3	海关官员	0.00%	0
4	其他	0.00%	0
	总计	100%	9

Q2 - Please indicate to what extent you agree with the statements below.

#	Question	Strongly disagree		Somewhat disagree		Neither agree nor disagree		Somewhat agree		Strongly agree		Total
1	I better understand how this technology can be used in my work after this training.	0.00%	0	0.00%	0	0.00%	0	33.33%	3	66.67%	6	9
2	I better understand the basics of operating this screening technology after this training.	0.00%	0	0.00%	0	0.00%	0	11.11%	1	88.89%	8	9
3	I better understand the theory (e.g. analytical technique such as spectroscopy) underpinning this screening technology after this training.	0.00%	0	0.00%	0	11.11%	1	11.11%	1	77.78%	7	9
4	I feel more confident preparing and analyzing samples using this screening technology after this training.	0.00%	0	0.00%	0	0.00%	0	11.11%	1	88.89%	8	9
5	I feel more confident interpreting the results obtained using this screening technology after this training.	0.00%	0	0.00%	0	0.00%	0	33.33%	3	66.67%	6	9

问题 2-请说明你在多大程度上同意下面的陈述。

#	问题	非常不同意		有点不同意		既不同意也不反对		有点同意		强烈同意		合计
1	经过这次培训，我更好地理解了这项技术如何应用到我的工作中。	0.00%	0	0.00%	0	0.00%	0	33.33%	3	66.67%	6	9
2	在这次培训之后，我更好地了解了操作这种筛选技术的基本知识。	0.00%	0	0.00%	0	0.00%	0	11.11%	1	88.89%	8	9
3	在这次培训之后，我更好地理解了支撑这种筛选技术的理论（如光谱分析技术）。	0.00%	0	0.00%	0	11.11%	1	11.11%	1	77.78%	7	9
4	经过这次培训，我对使用这种筛选技术准备和分析样本更有信心。	0.00%	0	0.00%	0	0.00%	0	11.11%	1	88.89%	8	9
5	经过这次培训，我对解释使用这种筛选技术获得的结果更有信心	0.00%	0	0.00%	0	0.00%	0	33.33%	3	66.67%	6	9

Q3 - Please indicate to what extent you agree with the statements below.

#	Question	Strongly disagree		Somewhat disagree		Neither agree nor disagree		Somewhat agree		Strongly agree		Total
1	The training provided sufficient time to understand the basics of operating this screening technology.	0.00%	0	0.00%	0	0.00%	0	11.11%	1	88.89%	8	9
2	The length and level of detail covered in this training would be sufficient to train colleagues in similar professional positions to myself.	0.00%	0	0.00%	0	0.00%	0	22.22%	2	77.78%	7	9
3	I feel confident teaching someone else how to use this screening technology.	0.00%	0	0.00%	0	0.00%	0	22.22%	2	77.78%	7	9
4	I think this technology would be valuable in helping me carry out aspects of my work related medicine sampling and testing.	0.00%	0	0.00%	0	0.00%	0	44.44%	4	55.56%	5	9

问题 3-请说明您在多大程度上同意下面的陈述。

#	问题	非常不同意		有点不同意		既不同意也不反对		有点同意		强烈同意		合计
1	培训提供了足够的时间来了解操作这种筛选技术的基本知识。	0.00%	0	0.00%	0	0.00%	0	33.33%	3	66.67%	6	9
2	本次培训所涵盖的时间和详细程度足以培训与我担任类似专业职位的同事。	0.00%	0	0.00%	0	0.00%	0	11.11%	1	88.89%	8	9

3	我有信心教别人如何使用这种筛选技术。	0.00%	0	0.00%	0	11.11%	1	11.11%	1	77.78%	7	9
4	我认为这项技术将有助于我开展与工作有关的药物取样和检测方面的工作。	0.00%	0	0.00%	0	0.00%	0	11.11%	1	88.89%	8	9

Q4 - In your opinion, how long would you need training on this screening technology to be for you to become a basic user?

问题 4：在您看来，要成为一个基本用户，您需要接受多长时间这种筛选技术的培训?

#	Answer	%	Count
1	Less than one day	44.44%	4
2	Between one day and one week	55.56%	5
3	More than one week	0.00%	0
	Total	100%	9

#	回答	%	计数
1	少于一天	44.44%	4
2	介于一天和一周之间	55.56%	5
3	3 多于一周	0.00%	0
	总计	100%	9

Q5 - In your opinion, how long would you need a training on this screening

technology to be for you to become an advanced user?

问题 5：在你看来，要成为一名高级用户，您需要接受多长时间这种筛选技术的培训?

#	Answer	%	Count
1	Less than one day	0.00%	0
2	Between one day and one week	77.78%	7
3	More than one week	22.22%	2
	Total	100%	9

#	回答	%	计数
1	少于一天	0.00%	0
2	介于一天和一周之间	77.78%	7
3	3 多于一周	22.22%	2
	总计	100%	9

Q6 - In your opinion, how long would you need a training on this screening technology to be for you to be able to train colleagues?

问题 6：在你看来，您需要接受多长时间这种筛选技术的培训才能培训你的同事?

#	Answer	%	Count
1	Less than one day	0.00%	0
2	Between one day and one week	88.89%	8
3	More than one week	11.11%	1
	Total	100%	9

#	回答	%	计数
1	少于一天	0.00%	0
2	介于一天和一周之间	88.89%	8
3	3 多于一周	11.11%	1

	总计	100%	9

Q7 - Are there any additional comments you have regarding the training and/or screening technology?

问题 7：关于培训和/或筛选技术，您还有其他意见吗？

Good timing of the training. The training was very effective and it gave us an opportunity to learn how important these technologies are

培训的时机很好，培训非常有效，它让我们有机会了解这些技术的重要性。

the device should be equipped with rechargeable batteries such as in mobile devices to make it easier to use especially if one is in remote places where access to shops to procure the AA batteries may be limited

该设备应配备可充电电池，如移动设备，以便于使用，尤其是在偏远地区，商店购买 AA 电池的通道可能受到限制时。