<table>
<thead>
<tr>
<th>BioFire Diagnostics LLC</th>
<th>Randox Biosciences</th>
<th>Randox Biosciences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salt Lake City</td>
<td>Crumlin, UK</td>
<td>Crumlin, UK</td>
</tr>
<tr>
<td>(800) 735-6544;</td>
<td>+44 (0)28 9442 2413;</td>
<td>+44 (0)28 9442 2413;</td>
</tr>
</tbody>
</table>

1. What is the brand name of your company’s microbiology system?
2. Specify the authorizing agency, type, and year of the product’s regulatory authorizations.
3. What are the dimensions of the named product (H x W x D, in inches)?
4. What is the intended use or primary function of the product?
5. What types of specimen/sample does the product employ?
6. What types of diseases, conditions, or analytes does the system detect?
7. Which methodology or clinical standard of care does the product use?
8. If you answered “other,” explain briefly.
9. What is the product’s maximum specimen capacity and throughput under ideal conditions?
10. Briefly describe any automation or connectivity features or options.
11. What is the typical training time for the product?
12. What types of technical support are available?
13. What capabilities, features, or accessories distinguish this product from others on the market?

### BioFire Diagnostics LLC

- **FilmArray**
- CE mark, 2015; FDA 510(k), 2015.
- 21 inches x 36 inches x 24 inches
- In vitro diagnostic using a multiplex polymerase chain reaction (PCR)-based biochip array; simultaneous detection of 22 viral and bacterial infections of the upper and lower respiratory tracts.
- Blood culture, cerebrospinal fluid, nasopharyngeal swab, stool.
- Identification of pathogens causing bloodstream infections, infectious diarrhea, meningitis/encephalitis, and respiratory illness.
- Multiplex, real-time polymerase chain reaction.
- 176 samples per day.
- Laboratory information system interfacing capability.
- n/a
- Phone, e-mail, in-person.
- Sample-to-answer system that requires minimal hands-on time and reports results for a comprehensive list of pathogens, depending on the syndrome, in about 1 hour.
- Statistics for molecular tests (summarizes all specimen types)
- Other

### Randox Biosciences

- Respiratory pathogen (RP) multiplex array
- CE mark, year n/a.
- Evidence Investigator (EI) analyzer: 29.5 inches x 16.5 inches x 18.9 inches; test unit size: 9 mm x 9 mm.
- Bronchoalveolar lavage, nasopharyngeal swab, saliva, sputum.
- RP nucleic acid targets.
- Biochip microarray-based approach using simple chemistries similar to enzyme-linked immunosorbent assay.
- A maximum of 54 multiplex tests in a single EI imaging run.
- Multiplex PCR reactions performed on separate thermal cycler; amplicon hybridization and conjugation steps automated using EI analyzer package thermoshakers.
- 3 days to complete Randox accredited standards.
- Remote diagnostics available globally; gold, silver, and bronze service packages include annual preventive maintenance visits.
- Simultaneous detection of routine and frequently requested bacterial and viral infections; EI allows throughput flexibility; 3–54 tests (1188 results) in a single run; multiple protocol stop points to harmonize with laboratory workflow; EI performs protein and nucleic acid multiplex tests; suitable for a multidisciplinary pathology laboratory.

### Randox Biosciences

- Sexually transmitted infection (STI) multiplex array
- CE mark, 2015.
- Evidence Investigator (EI) analyzer: 29.5 inches x 16.5 inches x 18.9 inches; test unit size: 9 mm x 9 mm.
- Urine, urogenital swab.
- STI nucleic acid targets.
- Biochip microarray-based approach using simple chemistries similar to enzyme-linked immunosorbent assay.
- A maximum of 54 multiplex tests in a single EI imaging run.
- Biochip array chemiluminescent signatures are automatically detected by charged-coupled device camera on the EI platform and reported in approximately 3 minutes.

### Dimensions

- **BioFire Diagnostics LLC**
  - 7.5 inches x 4.5 inches x 9.5 inches
- **Randox Biosciences**
  - 9 mm x 9 mm
- **Randox Biosciences**
  - 35.6 inches x 65.6 inches x 4800 system

### Technology

- **BioFire Diagnostics LLC**
  - FilmArray
  - CE mark, 2015; FDA 510(k), 2015.
  - In vitro diagnostic using a multiplex polymerase chain reaction (PCR)-based biochip array; simultaneous detection of 22 viral and bacterial infections of the upper and lower respiratory tracts.
  - Blood culture, cerebrospinal fluid, nasopharyngeal swab, stool.
  - Identification of pathogens causing bloodstream infections, infectious diarrhea, meningitis/encephalitis, and respiratory illness.
  - Multiplex, real-time polymerase chain reaction.
  - 176 samples per day.
  - Laboratory information system interfacing capability.
  - n/a
  - Phone, e-mail, in-person.
  - Sample-to-answer system that requires minimal hands-on time and reports results for a comprehensive list of pathogens, depending on the syndrome, in about 1 hour.

- **Randox Biosciences**
  - Respiratory pathogen (RP) multiplex array
  - CE mark, year n/a.
  - Evidence Investigator (EI) analyzer: 29.5 inches x 16.5 inches x 18.9 inches; test unit size: 9 mm x 9 mm.
  - Bronchoalveolar lavage, nasopharyngeal swab, saliva, sputum.
  - RP nucleic acid targets.
  - Biochip microarray-based approach using simple chemistries similar to enzyme-linked immunosorbent assay.
  - A maximum of 54 multiplex tests in a single EI imaging run.
  - Multiplex PCR reactions performed on separate thermal cycler; amplicon hybridization and conjugation steps automated using EI analyzer package thermoshakers.
  - 3 days to complete Randox accredited standards.
  - Remote diagnostics available globally; gold, silver, and bronze service packages include annual preventive maintenance visits.
  - Simultaneous detection of routine and frequently requested bacterial and viral infections; EI allows throughput flexibility; 3–54 tests (1188 results) in a single run; multiple protocol stop points to harmonize with laboratory workflow; EI performs protein and nucleic acid multiplex tests; suitable for a multidisciplinary pathology laboratory.

### Sample Types

- **BioFire Diagnostics LLC**
  - Throat swabs.
  - Nasopharyngeal swabs.

- **Randox Biosciences**
  - Urine, urogenital swab.

### Authorizations

- **BioFire Diagnostics LLC**
  - CE mark, 2013; FDA 510(k), 2015.

- **Randox Biosciences**
  - CE mark, 2013; FDA 510(k), 2015.
<table>
<thead>
<tr>
<th>Roche Diagnostics Corp</th>
<th>Roche Diagnostics Corp</th>
<th>Roche Diagnostics Corp</th>
<th>Roche Diagnostics Corp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indianapolis</td>
<td>Indianapolis</td>
<td>Indianapolis</td>
<td>Indianapolis</td>
</tr>
<tr>
<td>(800) 428-5076;</td>
<td>(800) 428-5076;</td>
<td>(800) 428-5076;</td>
<td>(800) 428-5076;</td>
</tr>
<tr>
<td>usdiagnostics.roche.com</td>
<td>usdiagnostics.roche.com</td>
<td>usdiagnostics.roche.com</td>
<td>usdiagnostics.roche.com</td>
</tr>
<tr>
<td>Cobas C. diff assay</td>
<td>Cobas MRSA/SA assay</td>
<td>Cobas Strep A assay</td>
<td>Cobas influenza A/B</td>
</tr>
<tr>
<td>for use on the Cobas</td>
<td>for use on the Cobas</td>
<td>for use on the Cobas</td>
<td>assay for use on the</td>
</tr>
<tr>
<td>4800 system</td>
<td>4800 system</td>
<td>4800 system</td>
<td>Cobas Liat system</td>
</tr>
<tr>
<td>CE mark, 2013; FDA</td>
<td>CE mark, 2013; FDA</td>
<td>CLIA waived, 2015;</td>
<td>CLIA waived, 2015;</td>
</tr>
<tr>
<td>Instrument: 35.6 inches</td>
<td>Instrument: 35.6 inches</td>
<td>7.5 inches x 4.5 inches</td>
<td>7.5 inches x 4.5 inches</td>
</tr>
<tr>
<td>x 65.6 inches x 30.1</td>
<td>x 65.6 inches x 30.1</td>
<td>x 9.5 inches</td>
<td>x 9.5 inches</td>
</tr>
<tr>
<td>inches; analyzer: 19.6</td>
<td>inches; analyzer: 19.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>inches x 22.6 inches</td>
<td>inches x 23.1 inches</td>
<td></td>
<td></td>
</tr>
<tr>
<td>An automated, qualitative in vitro diagnostic test for the direct detection of the toxin B gene of toxigenic <em>Clostridium difficile</em> (<em>C. difficile</em>).</td>
<td>A qualitative in vitro diagnostic assay for the direct detection of methicillin-resistant <em>Staphylococcus aureus</em> (MRSA) and <em>S. aureus</em> (SA) DNA.</td>
<td>A qualitative in vitro diagnostic test for the detection of <em>Streptococcus pyogenes</em> (Group A β-hemolytic <em>Streptococcus</em>, Strep A) in patients with signs and symptoms of pharyngitis.</td>
<td>Automated multiplex assay for the rapid in vitro qualitative detection and discrimination of influenza A virus and influenza B virus RNA in patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors.</td>
</tr>
<tr>
<td>Uniformed (liquid or soft) stool specimens obtained from patients suspected of having <em>C. difficile</em> infection.</td>
<td>Nasal swabs.</td>
<td>Throat swabs.</td>
<td>Nasopharyngeal swabs.</td>
</tr>
<tr>
<td><em>C. difficile</em></td>
<td>MRSA and SA.</td>
<td><em>Streptococcus pyogenes</em> (Group A β-hemolytic <em>Streptococcus</em>, Strep A).</td>
<td>Influenza A and influenza B viruses.</td>
</tr>
<tr>
<td>q Sputum adequacy by Gram stain</td>
<td>q Sputum adequacy by Gram stain</td>
<td>q Sputum adequacy by Gram stain</td>
<td>q Sputum adequacy by Gram stain</td>
</tr>
<tr>
<td>q Enrichment cultures</td>
<td>q Enrichment cultures</td>
<td>q Enrichment cultures</td>
<td>q Enrichment cultures</td>
</tr>
<tr>
<td>q Blood cultures</td>
<td>q Blood cultures</td>
<td>q Blood cultures</td>
<td>q Blood cultures</td>
</tr>
<tr>
<td>q Fluorochrome staining for acid-fast bacteria</td>
<td>q Fluorochrome staining for acid-fast bacteria</td>
<td>q Fluorochrome staining for acid-fast bacteria</td>
<td>q Fluorochrome staining for acid-fast bacteria</td>
</tr>
<tr>
<td>q Parasitemia (%)</td>
<td>q Parasitemia (%)</td>
<td>q Parasitemia (%)</td>
<td>q Parasitemia (%)</td>
</tr>
<tr>
<td>q Cell lines and incubation time for virus isolation</td>
<td>q Cell lines and incubation time for virus isolation</td>
<td>q Cell lines and incubation time for virus isolation</td>
<td>q Cell lines and incubation time for virus isolation</td>
</tr>
<tr>
<td>q Statistics for molecular tests (summarizes all specimen types)</td>
<td>q Statistics for molecular tests (summarizes all specimen types)</td>
<td>q Statistics for molecular tests (summarizes all specimen types)</td>
<td>q Statistics for molecular tests (summarizes all specimen types)</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Real-time polymerase chain reaction testing.</td>
<td>Real-time polymerase chain reaction testing.</td>
<td>Real-time polymerase chain reaction testing.</td>
<td>Real-time polymerase chain reaction testing.</td>
</tr>
<tr>
<td>The instrument can run up to 96 tests at a time (84 samples and 2 controls) in under 4 hours.</td>
<td>The instrument can run up to 96 tests at a time (84 samples and 2 controls) in under 4 hours.</td>
<td>The instrument can conduct one test at a time with a turnaround time of 15 minutes.</td>
<td>The instrument can conduct one test at a time with a turnaround time of 20 minutes.</td>
</tr>
<tr>
<td>Simplified sample preanalytics; automated sample preparation; automated amplification and detection; laboratory information system connectivity; ability to parallel process multiple analytes (MRSA/MSSA, <em>C. difficile</em>, herpes simplex virus 1 and 2).</td>
<td>Direct sample vial loading; automated sample preparation; automated amplification and detection; laboratory information system connectivity; ability to parallel process multiple analytes (MRSA/MSSA, <em>C. difficile</em>, herpes simplex virus 1 and 2).</td>
<td>Health Level Seven International enabled connectivity.</td>
<td>Health Level Seven International enabled connectivity.</td>
</tr>
<tr>
<td>Waived status under the Clinical Laboratory Improvement Amendments of 1988; no training required.</td>
<td>Waived status under the Clinical Laboratory Improvement Amendments of 1988; no training required.</td>
<td>Waived status under the Clinical Laboratory Improvement Amendments of 1988; no training required.</td>
<td>Waived status under the Clinical Laboratory Improvement Amendments of 1988; no training required.</td>
</tr>
<tr>
<td>Directly through Roche Diagnostics.</td>
<td>Directly through Roche Diagnostics.</td>
<td>Directly through Roche Diagnostics.</td>
<td>Directly through Roche Diagnostics.</td>
</tr>
<tr>
<td>Flexibility to adapt to variable testing volumes while maintaining optimal workflow and cost efficiency; broad strain coverage validation for detection confidence.</td>
<td>Up to 90% less total hands-on time compared to other test options; provides two results in one test (MRSA surveillance screening and presurgical SA screening).</td>
<td>Fast detection of <em>Streptococcus pyogenes</em> in throat swab specimens, with a 15-minute turnaround time.</td>
<td>Fast detection and differentiation of influenza A and B, with a 20-minute turnaround time.</td>
</tr>
</tbody>
</table>