

Infected Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers

Docket Folder Summary









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Docket ID: FDA-2016-D-0971 Agency: Food and Drug Administration (FDA)

Parent Agency: Department of Health and Human Services (HHS)

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
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|  | Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification... | Comment Period Closed
Sep 12, 2016 11:59 PM ET |
| Notice | Posted: 08/11/2016 ID: FDA-2016-D-0971-0005 | |
|  | Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification... | Comment Period Closed
Aug 11, 2016 11:59 PM ET |
| Notice | Posted: 05/13/2016 ID: FDA-2016-D-0971-0001 | |
|  | Request for Extension from Advanced Medical Technology Association (AdvaMed)  | Comment Period Closed |
| Other | Posted: 08/15/2016 ID: FDA-2016-D-0971-0006 | |
|  | Request for Extension from Advanced Medical Technology Association (AdvaMed)  | Comment Period Closed |
| Other | Posted: 08/15/2016 ID: FDA-2016-D-0971-0007 | |
|  | Guidance for Infectious Disease Next Generation Sequencing Based Diagnostic Devices Microbial...  | Comment Now! |
| Other | Posted: 05/16/2016 ID: FDA-2016-D-0971-0002 | |

Supporting Documents

No documents available.

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|  | <i>See Attached</i>  | View Comment | Posted: 08/24/2016 ID: FDA-2016-D-0971-0015 |
|  | <i>The Critical Path Institute is submitting comments to this draft guidance on behalf of the members of the Critical Path to TB Regimens (CPTR). FDA is to be...</i>  | View Comment | Posted: 08/15/2016 ID: FDA-2016-D-0971-0010 |
|  | <i>Please find attached comments from Microbiologics.</i>  | View Comment | Posted: 08/15/2016 ID: FDA-2016-D-0971-0011 |
|  | <i>See attached file(s)</i>  | | |

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See attached file for full response - brief summary: Oxford Nanopore welcomes the initiative of the FDA to develop guidelines to inform the safe and effective...

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