| FACT Virtual Inspection Agenda Example |
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| FACT Renewal InspectionCord Blood BankWashington DC, USA |
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| DAY/TIME TIME ZONE | Meeting Topic and Zoom Links | Attendees (name and role) |
| DAY 0 December 31, 2021 |
| TBD | Inspection Team Pre-Inspection MeetingZoom 5 | All inspectors |
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| DAY 1 January 1, 2022 TIME ZONE |
| 08:00 CT | Introductory MeetingZoom 1 | All inspectors, CBB DirectorCBB Medical DirectorCBB Collection Director(s)CBB Processing Facility DirectorQuality Unit Manager, Managers, SupervisorsOther leadershipInterpreters |
| 08:45 CT | Central Bank InspectionZoom 2 | Bank inspectorBank coordinator for inspectionTechnical support person, assistantInterpreter |
|  | Collection InspectionZoom 3  | Collection inspectorCollection coordinator for inspectionTechnical support person, assistantInterpreters |
|  | Processing InspectionZoom 4  | Processing inspectorProcessing facility coordinator for inspectionTechnical support person, assistantInterpreters |
| 10:30 CT | Break |
| 10:45 CT | Resume individual inspections |  |
| 12:00 CT | Lunch break | Everyone |
| 12:30 CT | Inspectors’ closed meetingZoom 5 | All inspectorsInterpreters |
| 13:00 CT | Resume individual inspections |  |
| 14:40 CT | BREAK |
| 15:00 CT | Resume individual inspections |  |
| 16:30 CT | Inspectors’ closed meetingZoom 5 | Review progress |
| 16:40 CT | Inspectors meet with Bank;notify applicant of expectations and schedule for the next dayZoom 1 | All inspectors and applicant participantsInterpreters |
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| DAY 2 January 2, 2022 TIME ZONE |
| 08:00 CT | Introduction to Day 2Zoom 1 | Inspectors and applicant participantsInterpreters |
| 08:30 CT | Resume individual inspections |  |
| 10:00 CT | Break |
| 10:30 CT | Resume individual inspections |  |
| 12:00 CT | Lunch BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 CT | Resume individual inspections |  |
| 15:00 CT | Inspectors’ meeting; plan Exit InterviewZoom 5 | All inspectors |
| 16:00 CT | EXIT INTERVIEWZoom 1 | All inspectorsApplicant participants and guestsInterpreters |

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| Contact Information |
| **ROLE** | **NAME** | **CELL PHONE NUMBER** |
| Team Leader |  |  |
| Bank Inspector  |  |  |
| Collection Inspector |  |  |
| Processing Inspector |  |  |
|  |  |  |
|  |  |  |
| CBB Director |  |  |
| CBB Medical Director |  |  |
| CBB Collection Director(s) |  |  |
| CBB Processing Facility Director |  |  |
| Quality Unit Manager |  |  |
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| FACT Accreditation Coordinator |  |  |

| AGENDA: Virtual Central Bank Inspection |
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| FACT Renewal InspectionCord Blood BankWashington DC, USA |
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| DAY/TIME TIME ZONE | Meeting Topic and Zoom Links | Attendees (name and role) |
| DAY 1 January 1, 2022 TIME ZONE |
| 08:00 CT | Introductory MeetingZoom 1 | All inspectors, CBB DirectorCBB Medical DirectorCBB Collection Director(s)CBB Processing Facility DirectorQuality Unit Manager, Managers, SupervisorsOther leadershipInterpreter |
| O8:45 CT | Central Bank InspectionReview Tour / Facility issuesEnvironmental / maintenance recordsZoom 2 | Bank inspectorBank coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:30 CT | BREAK |
| 10:45 CT | B2: Quality ManagementReview records, minutes [ID documents:]Zoom 2 | Bank inspectorBank coordinator for inspection [NAME: \_\_\_\_\_\_\_]Quality Unit Manager [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | Lunch Break | Everyone |
| 12:30 CT | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 CT | B1: Personnel records, training recordsZoom 2 | Bank inspectorBank coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 14:45 CT | BREAK |
| 15:00 CT | Document Review Part BZoom 2 | Bank inspectorBank coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 16:30 CT | Adjourn inspectionZoom 5  | Inspection Team meeting |
| 16:40 CT | Inspectors meet with Bank; notify applicant of expectations and schedule for the next day Zoom 1 | All inspectors and applicant participants |
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| DAY 2 January 2, 2022 TIME ZONE  |
| 08:00 CT | Introduction to Day 2 Zoom 1 | Inspectors and applicant participants |
| 08:30 CT | Review of relevant standards in Part EZoom 2 | Bank inspectorBank coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:00 CT | BREAK |
| 10:30 CT | Review of relevant standards in Part EZoom 2 | Bank inspectorBank coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | LUNCH BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 CT | Complete reviewZoom 2 | Bank inspectorBank coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 15:00 CT | Inspectors’ meeting; plan Exit InterviewZoom 5 | All inspectors |
| 16:00 CT | EXIT InterviewZoom 1 | All inspectors, applicant participants and invited guests |

| AGENDA: Virtual Collection Facility Inspection |
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| FACT Renewal InspectionCord Blood BankWashington DC, USA |
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| DAY/TIME TIME ZONE | Meeting Topic and Zoom Link | Attendees (name and role) |
| DAY 1 January 1, 2022 TIME ZONE  |
| 08:00 CT | Introductory MeetingLocation:Zoom 1 | All inspectors, CBB DirectorCBB Medical DirectorCBB Collection Director(s)CBB Processing Facility DirectorQuality Unit Manager, Managers, SupervisorsOther leadershipInterpreter |
| O8:45 CT | Collection Site #1/Non-fixed Collection Processes at the BankReview Tour / Facility issues Environmental / maintenance recordsZoom 3 | Collection inspectorCollection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:30 CT | BREAK |
| 10:45 CT | Mock procedure: discussion, clarification | Collection inspectorCollection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | LUNCH BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meetingZoom 5 | All inspectors  |
| 13:00 CT | Personnel records, training records Zoom 3 | Collection inspectorCollection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 13:45 CT | Collector InterviewsZoom 3 | Collection inspectorCollection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_]Collector(s) [NAME: \_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 14:40 CT | BREAK |  |
| 15:00 CT | Collection Site #2Review Tour / Facility issues Environmental / maintenance recordsZoom 3 | Collection inspectorCollection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 16:30 CT | Adjourn inspection Zoom 5 | Inspection Team meeting |
| 16:40 CT | Inspectors meet with Bank; notify applicant of expectations and schedule for the next dayZoom 1 | All inspectors and applicant participants |
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| DAY 2 January 2, 2022 TIME ZONE  |
| 08:00 CT | Introduction to Day 2 Zoom 1 | Inspectors and applicant participants |
| 08:30 CT | Review labeling and shipping; complete checklist Zoom 3 | Collection inspectorCollection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:00 CT | Break |
| 10:30 CT | Zoom 3 | TBD |
| 12:00 CT | LUNCH BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 CT | Review of relevant standards in Part B/C/EZoom 3 | Collection inspectorCollection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 15:00 CT | Inspectors’ meeting; plan Exit InterviewZoom 5 | All inspectors |
| 16:00 CT | EXIT Interview. Zoom 1 | All inspectors, applicant participants and invited guests |

| AGENDA: Virtual Processing Facility Inspection |
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| FACT Renewal InspectionCord Blood BankWashington DC, USA |
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| DAY/TIME TIME ZONE | Meeting Topic and Zoom Link | Attendees (name and role) |
| DAY 1 January 1, 2022 TIME ZONE  |
| 08:00 CT | Introductory MeetingZoom 1 | All inspectors, CBB DirectorCBB Medical DirectorCBB Collection Director(s)CBB Processing Facility DirectorQuality Unit Manager, Managers, SupervisorsOther leadershipInterpreter |
| O8:45 CT | Cell Processing InspectionReview Tour / Facility issues; Environmental / maintenance records; Facilities, equipment, materials managementZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10;30 CT | BREAK |
| 10:45 CT | Mock processing and cryopreservation procedure: discussion, clarificationZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | Lunch Break | Everyone |
| 12:30 CT | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 CT | OperationsZoom 4 | Interview operations staff [NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 13:30 CT | Document Review Part DZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 14:40 CT | BREAK |
| 15:00 CT | Review processing recordsZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 16:30 CT | Adjourn inspectionZoom 5 | Inspection Team meeting |
| 16:40 CT | Inspectors meet with Bank; notify applicant of expectations and schedule for the next dayZoom 1 | All inspectors and applicant participants |
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| DAY 2 January 2, 2022 TIME ZONE  |
| 08:00 CT | Introduction to Day 2 Zoom 1 | Inspectors and applicant participants |
| 08:30 CT | Review records/labelingZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:00 CT | BREAK |
| 10:30 CT | Finish records/labelingZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | LUNCH BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 CT | Off-site storage checklist or review of relevant standards in Part B/D/EZoom 4  | Off-site storage staff – if applicable [NAME: \_\_\_\_] Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 15:00 CT | Inspectors’ meeting; plan Exit Interview Zoom 5 | All inspectors |
| 16:00 CT | EXIT Interview. Zoom 1 | All inspectors, applicant participants and invited guests |

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| Persons Interviewed During the Inspection |
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| Cord Blood Bank |
| **NAME** | **POSITION / ROLE IN BANK** |
|  | CBB Director |
|  | CBB Medical Director |
|  | CBB Collection Director(s) |
|  | CBB Processing Facility Director |
|  | Quality Unit Manager |
|  | Bank staff  |
|  |  |
|  |  |
|  |  |
|  |  |
| CB Unit Collection |
|  | CBB Collection Director(s) |
|  | Quality Unit Manager |
|  | Collection Staff |
|  | Collection Staff |
|  |  |
|  |  |
|  |  |
| CBB Processing Facility |
|  | CBB Processing Facility Director |
|  | Quality Unit Manager |
|  | Processing Staff |
|  | Processing Staff |
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