



QA: QA

Bill Stimson, QA/Compliance Manager  
MIDI Labs, Inc.  
125 Sandy Drive  
Newark, DE 19713

**BECHTEL SAIC COMPANY, LLC (BSC) QUALITY ASSURANCE (QA) SUPPLIER  
AUDIT REPORT BSC-SA-02-023 OF MIDI LABS, INC.**

Enclosed is the Supplier Audit Report BSC-SA-02-023 of MIDI Labs, Inc. in Newark, Delaware performed on April 24-25, 2002. The audit evaluated the implementation and effectiveness of the Quality Program in meeting the requirements of the BSC procurement documents.

The audit revealed effective implementation of the MIDI Labs, Inc. Quality Program with the exception of two conditions adverse to quality in the areas of Procurement Document Control, Control of Purchased Items and Services, and Sample Control. The conditions adverse to quality are documented in Deficiency Reports (DRs) BSC(V)-02-D-111 and -112.

This audit is considered complete and closed as of the date of this letter.

If you have any questions, please contact either Richard L. Maudlin at (702) 295-2961 or Daniel A. Klimas at (702) 295-2665.

*Robert P. Keele* for  
Donald T. Krishna, Manager  
Quality Assurance

5-28-02  
Date Signed

RLM:bw-0528022794

Enclosure:  
Supplier Audit Report BSC-SA-02-023

*NP 5/28/02*  
*WHL-11*

May 28, 2002

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cc w/encl:

L. H. Barrett, DOE/HQ (RW-2) FORS  
G. K. Beall, BSC, Las Vegas, NV  
L. W. Bradshaw, Nye County, Pahrump, NV  
Margaret Chu, DOE/HQ (RW-1) FORS  
J. R. Dyer, DOE/YMSCO, Las Vegas, NV  
Leonard Fiorenzi, Eureka County, Eureka, NV  
Birdie Hamilton-Ray, DOE/YMSCO, Las Vegas, NV  
Geneva Hollis, Nye County, Tonopah, NV  
Alan Kalt, Churchill County, Fallon, NV  
D. A. Klimas, BSC, Las Vegas, NV  
D. T. Krishna, BSC, Las Vegas, NV  
Josie Larson, White Pine County, Ely, NV  
Robert Latta, NRC, Las Vegas, NV  
R. R. Loux, State of Nevada, Carson City, NV  
S. W. Lynch, State of Nevada, Carson City, NV  
George McCorkell, Esmeralda County, Goldfield, NV  
Mifflin and Associates, Las Vegas, NV  
Ram Murthy, DOE/OQA, Las Vegas, NV  
Irene Navis, Clark County, Las Vegas, NV  
Andrew Remus, County of Inyo, Independence, CA  
Judy Shankle, Mineral County, Hawthorne, NV  
N. K. Stablein, NRC, Rockville, MD  
Lola Stark, Lincoln County, Caliente, NV  
D. D. vonderLinden, BSC, Las Vegas, NV  
N. H. Williams, BSC, Las Vegas, NV  
B. L. Wilson, BSC, Las Vegas, NV  
Mickey Yarbro, Lander County, Battle Mountain, NV

cc w/encl:

R. W. Andrews, BSC, Las Vegas, NV  
T. W. Doering, BSC, Las Vegas, NV  
R. L. Hand, BSC, Las Vegas, NV  
J. M. Horn, BSC/LLNL, Livermore, CA  
M. H. Kohler, BSC/LLNL, Livermore, CA  
R. L. Maudlin, BSC, Las Vegas, NV  
M. T. Peters, BSC/LANL, Las Vegas, NV  
Tammy Summers, BSC/LLNL, Livermore, CA  
Roxanna VanDillen, BSC, Las Vegas, NV  
C. C. Warren, BSC/LLNL, Livermore, CA

**BECHTEL SAIC COMPANY, LLC (BSC)  
QUALITY ASSURANCE (QA)  
SUPPLIER AUDIT REPORT**

**QA:QA**

1. **SUPPLIER AUDIT NUMBER:** BSC-SA-02-023
2. **DATES PERFORMED:** April 24-25, 2002
3. **SUPPLIER NAME:** MIDI Labs, Inc.
4. **SUPPLIER LOCATION:** Newark, Delaware
5. **SERVICES/ITEMS PROVIDED:** DNA Isolation, PCR amplification of the 16SrRNA, and sequencing of the 16SrRNA gene for bacterial identification.
6. **AUDIT SCOPE:** An evaluation of the implementation and effectiveness of the MIDI Labs, Inc. Quality Assurance Program to meet BSC procurement documents and included the areas found deficient as a result of the previous BSC Supplier Audit BSC-SA-01-032.
7. **QA PROGRAM ELEMENTS EVALUATED:** Quality Assurance Program, Procurement Document Control, Control of Purchased Items and Services, Control of Measuring and Test Equipment, Corrective Action, and Sample Control.
8. **SUPPLIER QUALITY PROGRAM DOCUMENT AND REVISION AUDITED:**  
MIDI Labs, Inc. Quality Manual, Revision A, dated 10/30/2000
9. **BSC APPLICABLE PROCUREMENT DOCUMENTS:**  
BSC Purchase Order TA003036
10. **AUDIT TEAM MEMBERS:**  
**LEAD:** Richard L. Maudlin, BSC QA  
**MEMBERS:** None
11. **OBSERVERS:** None
12. **PERSONNEL CONTACTED DURING AUDIT:**  
Bill Stimson, QA Manager, MIDI Labs, Inc.  
Margaret Riehman, Lab Manager, MIDI Labs, Inc.  
LeAnne Gandolfo, Senior Sequencing Technician, MIDI Labs, Inc.

13. **OVERALL EFFECTIVENESS OF THE SUPPLIERS QA PROGRAM IMPLEMENTATION:**

SATISFACTORY   X  

UNSATISFACTORY \_\_\_\_\_

IF CONSIDERED UNSATISFACTORY –DESCRIBE QA ELEMENT AND CAUSE: N/A

14. **FOLLOW-UP REQUIRED:**

\_\_\_\_\_ NO FOLLOW-UP AUDIT OR SURVEILLANCE REQUIRED

\_\_\_\_\_ SURVEILLANCE

\_\_\_\_\_ FOLLOW-UP AUDIT

  X   DETERMINATION BASED ON IMPACT WHEN CAR/DR CLOSED

15. **SUPPLIER STATUS:**

**AUDIT SCHEDULE**

\_\_\_\_\_ REMAIN ON QSL WITH TRIENNIAL AUDIT SCHEDULE

  X   REMAIN ON QSL WITH ANNUAL AUDIT SCHEDULE

Audits or surveillances prior to the next scheduled audit may be performed based on QA program changes, scope of work changes, and/or supplier performance as deemed necessary.

**RESTRICTIONS**

  X   NONE

\_\_\_\_\_ YES

IF YES – RESTRICTION IS: N/A

16. **AUDIT DETAILS:**

Details of the audit, along with the objective evidence reviewed are contained within the audit checklist, which is available from the BSC Records Processing Center.

17. **AUDIT FINDINGS:**

TOTAL CONDITIONS ADVERSE TO QUALITY:           Two

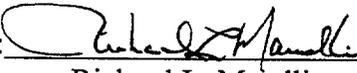
**CONDITIONS ADVERSE TO QUALITY BRIEF DESCRIPTION:**

Document Type and Number	Description
Deficiency Report BSC(V)-02-D-111	<p>A. QSP 0410, Section 2.0, states in part: "The PO should contain appropriate technical and quality requirements for the item or service being ordered."</p> <p>B. QSP 0410, Section 5.0, states in part: "Lab personnel receive the order and verifies that the finished item complies with PO requirements. Verification can include reviewing objective evidence for conformance to the PO requirements...."</p> <p>C. QSP 0411, Section 3.2, states in part: "The QA/Compliance Manager is responsible for evaluating the potential new supplier....Evaluation of applicable quality system documentation or records....quality manual...."</p> <p>Contrary to the requirements:</p> <p>A. MIDI Labs, Inc. purchase orders PO 1461, dated 01/18/2002; PO 1464, dated 01/21/2002; and PO 1474, dated 02/12/2002 for calibration services failed to include quality requirements.</p> <p>B. Documentation supporting the calibration of MIDI Labs, Inc. measuring and test equipment was not reviewed against the requirements of the MIDI Labs, Inc. purchase orders 1461, 1464, and 1474.</p> <p>C. No documentation could be provided to reflect that MIDI Labs, Inc. QA/Compliance Manager had reviewed the quality manuals for MIDI Labs, Inc. suppliers Pro-Lab, Ranin Service Center, and Delval Balance Service, who provide calibration services.</p>
Deficiency Report BSC(V)-02-D-112	<p>BSC TA 003036, Statement of Technical/Quality Requirements for DNA Sequence Analysis Services, Revision 00, Section II states in part: "Sample control and traceability shall be maintained at all times...."</p> <p>Contrary to the above requirements, MIDI does not have procedures in place, which describes the process for documenting and dispositioning samples which were not received. Example: LLNL provided a list of 61 samples to be submitted, however, MIDI Labs, Inc. could not account for all the samples on the LLNL list. One sample, #43, was missing. There was no documentation to support that, upon receipt, a sample was found to be missing and how that missing sample was to be dispositioned.</p>

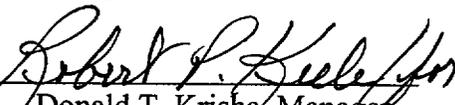
TOTAL RECOMMENDATIONS FOR IMPROVEMENT: None

RECOMMENDATIONS FOR IMPROVEMENT BRIEF DESCRIPTION: N/A

This audit is considered closed.

Prepared by:   
Richard L. Maudlin  
Audit Team Leader  
BSC Quality Assurance

Date: 05-23-02

Approved by:   
Donald T. Krishna, Manager  
BSC Quality Assurance

Date: 5-28-02