



GLOVE SAMPLING RECORD

LOT NUMBER: _____

DATE: _____

TECHNICIAN TAKING SAMPLES:

WITNESS:

One line for each box taken. Size distribution should be proportionate to lot

SIZE ^a	TEST I.D.	LOT NUMBER	PALLET LOCATION ^b	CASE LOCATION ^c	CASE NUMBER
	A				
	B				
	C				
	D				
	E				
	F				
	G				
	H				
	I				
	J				
	K				
	L				



- a Size distribution of sample is proportionate to size distribution of lot, e.g. 20% of lot is small, 20% of sample is small.
- b For example: Case from top middle of pallet #7.
- c Box from bottom of case.

NOTES:

TECHNICIAN: _____

DATE: _____

QAU MANAGER/
OR AGENCY REP: _____

DATE: _____



COLLECTION PROCEDURE FOR GLOVES

Example: The invoice submitted with the entry indicates that each carton contains 10/100 boxes of product.

LATEX EXAMINATION GLOVES		
CARTONS	DESCRIPTION	QUANTITY
330	Textured - Large	330,000
900	Textured - Medium	900,000
300	Textured - Small	300,000
1530	Textured Glove Total	1,530,000
703	Regular - Large	703,000

TEXTURED GLOVES

Textured Gloves to Collect	Collect # Boxes	First Round of 80 Test # of Gloves
Large: $330/1530 \times 560^* = 121$	=> 2	8 + 9 = 17
Medium: $900/1530 \times 560^* = 330$	=> 4	11 +12 +12 +12 = 47
Small: $300/1530 \times 560^* = 110$	=>2	8 + 8 = 16
Totals	8	80 Gloves

* = minimum sample size for this size lot of Patient Examination Gloves per 21 CFR 800.

REGULAR GLOVES

Regular Collect

Since there is only 1 size => collect 6 boxes, test 80 gloves for the first round of regular gloves examined.

Repeat the same number of gloves tested if another round of 80 gloves is indicated based on examination results of the first round of 80 gloves tested.



EXHIBIT 21-A SAMPLE COLLECTION REPORT FORM

Broker's Reference No. _____
Port of Entry: _____
Importer/Broker of Record: _____
Name, Address, Phone: _____

Grower: _____ Shipper: _____ Address: _____

Description of Product: _____
Description of Container: _____
Brand Name: _____
Label Size: _____ Product Code: _____
Invoiced Quantity: _____ Actual Quantity: _____
Copy of Invoice Attached?: Y/N Package Label Attached?: Y/N
Carton Label Attached?: Y/N Bulk Label Attached?: Y/N
Warehouse/Freezer Lot No: _____
Address Where Sampled: _____
Method of Collection: _____
No. of Cartons/Drums Opened: _____
No. of Packages/Portions From Each: _____
Weight/Volume of Portion Collected: _____
Identified by Collector on Each Portion As:
Method of Sealing:
Date of Collection: _____ Signature:
Collector's Name:
Collector's Employer:
Supervising Federal Representative (if any)/Date:
Agency:
Signature:



EXHIBIT 21-B ANALYSIS REPORT FORMAT

Description of Product:
Broker's Reference No.:
FDA Sample No.: _____ Lab Sample No.
Date Received: _____ Seal Intact? Y/N
Condition of Sample: ___ Frozen ___ Refrigerated ___ Ambient
Sample Description (size, No. of portions):

Container Code, if present:
Portions Identified by Collector as:
Portions Agreed with Description: Y/N
Date Analysis Begins: _____ Date Analysis Completed:
Method Used (References and any modifications):

Analyst(s):
Number of Subsamples: _____ Amount Analyzed per sub:
Total Amount Analyzed: _____ Sample Composited: Y/N
How Composited:

NOTE: Clearly indicate on each analytical worksheet who did what part of the analysis, with signature(s) and date(s). Results: For example, in pesticides, report residues found in the sample. Report the values for the fortified crop, unfortified crop and blank. Equipment Used: Identify equipment (and parameters) used to weigh and process samples, analyze extracts, etc.

Laboratory Director's statement: Review of records indicate that the product and lot referred to in this report have ___ have not ___ been subject to prior analysis by this laboratory. If the lot has been subject to prior analysis by this laboratory, copies of the final results are hereto attached. The prior analysis was conducted on the following date(s) and covered by the following lab report number(s):

Signed: _____ Date

NOTICE: The knowing and willful making of any false, fictitious or fraudulent statements or representations in any manner within the jurisdiction of any department or agency of the United States is a matter subject to the provisions of Title 18 of the U.S. Code, Section 1001.

Importer's Statement: The analytical results submitted with this report include all analytical work related to this sample performed by this laboratory and all other laboratories that may have conducted the analysis.

Signed: _____ Date _____