

Program No 3992-S R3 Term 02/01/2025 To 01/31/2026 *up to 4 option years				
TITLE: Labels and Printer Ribbons				
ITEM NO.	DESCRIPTION	BASIS OF AWARD	UNIT RATE	(Contr #1 - E4) Pacific Barcode, Inc. Temecula, CA <b>COST</b>
<b>I. COMPLETE PRODUCT:</b>				
1.	ITEM 1: Extraction Label - Blank..... .....per roll.....	156	40.83	6,369.48
2.	ITEM 2: Morpher Label - Blank..... .....per roll.....	48	50.27	2,412.96
3.	ITEM 3: Form/Folder Label - Blank..... .....per roll.....	12	167.30	2,007.60
4.	ITEM 4: Standard Tray Label - Printed..... .....per set.....	11,000	0.473	5,203.00
5.	ITEM 5: Folder Label - Printed (incl. special kitting) .....per set.....	6,000	1.98	11,880.00
6.	ITEM 6: Specimen Processing Label - Printed (incl. special kitting).....per set.....	6,000	9.84	59,040.00
7.	ITEM 7: Batch LAN Label - Blank..... .....per label.....	45,000	0.0399	1,795.50
8.	ITEM 8: Custom Piggy Back Label - Blank..... .....per roll.....	18	198.38	3,570.84
9.	ITEM 9: General Purpose Resin - Printer Ribbon (EXT label printer).....each.....	24	7.10	170.40
10.	ITEM 10: L3 Wax/Resin - Printer Ribbon (Morphers) .....each.....	96	13.00	1,248.00
11.	ITEM 11: Premium Wax/Resin - Printer Ribbon (Label Printers 1 & 2).....each.....	120	28.89	3,466.80
<b>CONTRACTOR TOTALS</b>				<b>\$97,164.58</b>
<b>DISCOUNT</b>				
<b>DISCOUNTED TOTALS</b>				<b>\$97,164.58</b>
<b>JY 3/19/2025</b>				<b>AWARDED</b>

U.S. GOVERNMENT PUBLISHING OFFICE  
Southwest Region

GENERAL TERMS, CONDITIONS, AND SPECIFICATIONS  
For the Procurement of

**Labels and Printer Ribbons**

as requisitioned from the U.S. Government Publishing Office (GPO) by the

**Tripler Forensic Toxicology Drug Testing Laboratory**

Single Award

**TERM OF CONTRACT:** The term of this contract is for the period beginning **Date of Award** and ending **January 31, 2026** plus up to four (4) optional 12-month extension periods that may be added in accordance with the "OPTION TO EXTEND THE TERM OF THE CONTRACT" clause in SECTION 1 of this contract.

**\*\*PROGRAM 3992-S R3: THE SPECIFICATIONS HAVE BEEN EXTENSIVELY REVISED.\*\***

**BID OPENING:** Bids shall be opened virtually at **11:00 a.m.**, prevailing Eastern Standard Time, on **Tuesday, December 17, 2024** at the Government Publishing Office, Southwest Region. All parties interested in attending the bid opening shall email **bids@gpo.gov** prior to bid opening date to request a Microsoft Teams live stream link. The link will be emailed on the day of the bid opening.

**BID SUBMISSION:** Bidders must email bids to: **bids@gpo.gov** for this solicitation. No other method of bid submission will be accepted at this time. The program number and bid opening date must be specified in the subject line of the emailed bid submission. Bids received after 11:00am EST on the bid opening date specified above will not be considered for award.

**BIDDERS, PLEASE NOTE:** This program was formerly Program 1999-S. These specifications have been *extensively* revised; therefore, all bidders are cautioned to familiarize themselves with all portions of these specifications before bidding.

Abstract of contract prices are available at <https://www.gpo.gov/how-to-work-with-us/vendors/contract-pricing>.

For information of a technical nature *before* award, contact Jennifer Yarbrough at 707-748-1976 or [jiyarbrough@gpo.gov](mailto:jiyarbrough@gpo.gov).

## SECTION 1.- GENERAL TERMS AND CONDITIONS

**GPO CONTRACT TERMS:** Any contract which results from this Invitation for Bid will be subject to the applicable provisions, clauses, and supplemental specifications of GPO Contract Terms (GPO Publication 310.2, effective December 1, 1987 (Rev. 01-18)) and GPO Contract Terms, Quality Assurance Through Attributes Program for Printing and Binding (GPO Publication 310.1, effective May 1979 (revised 9-19)).

GPO Contract Terms (GPO Publication 310.2) – <https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/contractterms2018.pdf>

GPO QATAP (GPO Publication 310.1) – <https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/qatap-rev-09-19.pdf>.

**SUBCONTRACTING:** Subcontracting is not authorized.

**QUALITY ASSURANCE LEVELS AND STANDARDS:** The following levels and standards shall apply to these specifications:

Product Quality Levels:

- (a) Printing (page related) Attributes – Level III
- (b) Finishing (item related) Attributes – Level III

Inspection Levels (from ANSI/ASQC Z1.4):

- (a) Non-destructive Tests – General Inspection Level I.
- (b) Destructive Tests – Special Inspection Level S-2.

Specified Standards: The specified standards for the attributes requiring them shall be:

<u>Attribute</u>	<u>Specified Standard</u>
P-7. Type Quality and Uniformity	Approved Pre-award Test Samples

**OPTION TO EXTEND THE TERM OF THE CONTRACT:** The Government has the option to extend the term of this contract for a period of 12 months by written notice to the contractor not later than 30 days before the contract expires. If the Government exercises this option, the extended contract shall be considered to include this clause, except, the total duration of the contract may not exceed five (5) years as a result of, and including, any extension(s) added under this clause. Further extension may be negotiated under the “EXTENSION OF CONTRACT TERM” clause. See also “ECONOMIC PRICE ADJUSTMENT” for authorized pricing adjustment(s).

**EXTENSION OF CONTRACT TERM:** At the request of the Government, the term of any contract resulting from this solicitation may be extended for such period of time as may be mutually agreeable to the GPO and the contractor.

**ECONOMIC PRICE ADJUSTMENT:** The pricing under this contract shall be adjusted in accordance with this clause, provided that in no event will any pricing adjustment be made that would exceed the maximum permissible under any law in effect at the time of the adjustment. There will be no adjustment for orders placed during the first period specified below. Pricing will thereafter be eligible for adjustment during the second and any succeeding performance period(s). For each performance period after the first, a percentage figure will be calculated as described below and that figure will be the economic price adjustment for that entire next period. Pricing adjustments under this clause are not applicable to reimbursable postage or transportation costs, or to paper, if paper prices are subject to adjustment by separate clause elsewhere in this contract.

For the purpose of this clause, performance under this contract will be divided into successive periods. The first period will extend from **February 1, 2025 through January 31, 2026** and the second and any succeeding period(s) will extend for 12 months from the end of the last preceding period, except that the length of the final period may vary. The first day of the second and any succeeding period(s) will be the effective date of the economic price adjustment for that period.

Pricing adjustments in accordance with this clause will be based on changes in the seasonally adjusted “Consumer Price Index For All Urban Consumers - Commodities Less Food” (Index) published monthly in the CPI Detailed Report by the U.S. Department of Labor, Bureau of Labor Statistics.

The economic price adjustment will be the percentage difference between Index averages as specified in this paragraph. An index called the variable index will be calculated by averaging the monthly Indexes from the 12-month interval ending three (3) months prior to the beginning of the period being considered for adjustment. This average is then compared to the average of the monthly Indexes for the 12-month interval ending **October 31, 2024** called the base index. The percentage change (plus or minus) of the variable index from the base index will be the economic price adjustment for the period being considered for adjustment.

The Government will notify the contractor by contract modification specifying the percentage increase or decrease to be applied to invoices for orders placed during the period indicated. The contractor shall apply the percentage increase or decrease against the total price of the invoice less reimbursable postage or transportation costs and separately adjusted paper prices. Payment discounts shall be applied after the invoice price is adjusted.

**PRE-AWARD SURVEY:** In order to determine the responsibility of the prime contractor or any subcontractor, the Government reserves the right to conduct an on-site pre-award survey at the contractor's/subcontractor's facility or to require other evidence of technical, production, managerial, financial, and similar abilities to perform, prior to the award of a contract. As part of the financial determination, the contractor in line for award may be required to provide one or more of the following financial documents:

- 1) Most recent profit and loss statement
- 2) Most recent balance sheet
- 3) Statement of cash flows
- 4) Current official bank statement
- 5) Current lines of credit (with amounts available)
- 6) Letter of commitment from paper supplier(s)
- 7) Letter of commitment from any subcontractor

The documents will be reviewed to validate that adequate financial resources are available to perform the contract requirements. Documents submitted will be kept confidential and used only for the determination of responsibility by the Government. Failure to provide the requested information in the time specified by the Government may result in the Contracting Officer not having adequate information to reach an affirmative determination of responsibility.

**PRE-AWARD TESTING:** The contractor being considered for award may be required to demonstrate its ability to produce the items required in these specifications at the requisite quality level by completing a pre-award test. The Government reserves the right to waive the pre-award test if there is other evidence that, in the opinion of the Contracting Officer, indicates that the contractor being considered for award has the capability to successfully produce the items required.

For the pre-award test, the Government will furnish one (1) unit for each label Item (set, roll, or sheet) as a sample representative of the materials to be furnished under these specifications.

The prospective contractor must produce two (2) units for each label Item (set, roll, or sheet) in accordance with the requirements specified herein. Samples must be printed on the required stock as specified herein.

The pre-award test samples will be inspected and tested for accuracy and conformance of materials to the furnished specifications, and must comply with the specifications stated herein. *Important Note: Contractor is cautioned to carefully review Appendix B through Appendix I, to ensure labels will meet or exceed all requirements. No substitutions for label material or adhesive is allowed.*

The contractor is responsible for picking up furnished samples and delivering pre-award test samples to: Tripler Army Medical Center, ATTN: MCHK-FT, 1 Jarret White Rd. Bldg. 40, Tripler AMC, HI 96859.

Pre-award test samples must deliver no later than **20 workdays** from the date the furnished samples are made available for pickup.

If the pre-award test files are disapproved by the Government, the contractor may be permitted, at the option of the Government, additional time to correct defects or to submit additional test samples if so notified by the Contracting Officer.

In the event the revised test files are disapproved by the Government, the contractor shall be deemed to have failed to comply with the applicable requirements of these specifications and may be reason for a determination of non-responsibility.

**Failure to deliver the completed test samples within 20 workdays from the date the furnished samples are made available for pickup may disqualify the contractor from further consideration for award.**

All operations necessary in the performance of this test shall be performed at the facilities in which the contract production will be performed.

No charges will be allowed for costs incurred in the performance of this pre-award test.

**POST-AWARD CONFERENCE:** Unless waived by the Contracting Officer, the total requirements of the job as indicated in these specifications, will be reviewed by Government representatives with the contractor's representatives via teleconference, immediately after award.

**ASSIGNMENT OF JACKETS, PURCHASE AND PRINT ORDERS:** A GPO jacket number will be assigned and a purchase order issued to the contractor to cover work performed. The purchase order will be supplemented by an individual print order for each job placed with the contractor. The print order, when issued, will indicate the quantity to be produced and any other information pertinent to the particular order.

**ORDERING:** Items to be furnished under the contract shall be ordered by the issuance of print orders by the Government. Orders may be issued under the contract from **February 1, 2025 through January 31, 2026**, plus for such additional period(s) as the contract is extended. All print orders issued hereunder are subject to the terms and conditions of the contract. The contract shall control in the event of conflict with any print order. A print order shall be "issued" upon notification by the Government for purposes of the contract when it is electronically transmitted or otherwise physically furnished to contractor in conformance with the schedule.

**REQUIREMENTS:** This is a requirements contract for the items and for the period specified herein. Shipment/delivery of items or performance of work shall be made only as authorized by orders issued in accordance with the clause entitled "ORDERING." The quantities of items specified herein are estimates only, and are not purchased hereby. Except as may be otherwise provided in this contract, if the Government's requirements for the items set forth herein do not result in orders in the amounts or quantities described as "estimated," it shall not constitute the basis for an equitable price adjustment under this contract.

Except as otherwise provided in this contract, the Government shall order from the contractor all the items set forth which are required to be purchased by the Government activity identified on page 1.

The Government shall not be required to purchase from the contractor, requirements in excess of the limit on total orders under this contract, if any.

Orders issued during the effective period of this contract and not completed within that time shall be completed by the contractor within the time specified in the order, and the rights and obligations of the contractor and the Government respecting those orders shall be governed by the terms of this contract to the same extent as if completed during the effective period of this contract.

If shipment/delivery of any quantity of an item covered by the contract is required by reason of urgency prior to the earliest date that shipment/delivery may be specified under this contract, and if the contractor will not accept an order providing for the accelerated shipment/delivery, the Government may procure this requirement from another source.

The Government may issue orders which provide for shipment/delivery to or performance at multiple destinations.

Subject to any limitations elsewhere in this contract, the contractor shall furnish to the Government all items set forth herein which are called for by print orders issued in accordance with the "ORDERING" clause of this contract.

**ADDITIONAL EMAILED BID SUBMISSION PROVISIONS:** The Government will not be responsible for any failure attributable to the transmission or receipt of the emailed bid including, but not limited to, the following –

1. Illegibility of bid.
2. Emails over 10MB may be received by GPO due to size limitations for receiving emails.
3. The bidder's email provider may have different size limitations for sending email; however, bidders are advised not to exceed GPO's stated limit.
4. When the email bid is received by GPO, it will remain unopened until the specified bid opening time. Government personnel will not validate receipt of the emailed bid prior to bid opening. GPO will use the prevailing time (specified as the local time zone) and the exact time that the email is received by GPO's email server as the official time stamp for bid receipt at the specified location.

**PAYMENT:** Submitting invoices for payment via the GPO fax gateway (if no samples are required) utilizing the GPO barcode coversheet program application is the most efficient method of invoicing. Instruction for using this method can be found at the following web address:

<http://winapps.access.gpo.gov/fms/vouchers/barcode/instructions.html>

Invoices may also be mailed to: U.S. Government Publishing Office, Office of Financial Management, Attn: Comptroller, Stop: FMCE, Washington, DC 20401.

For more information about the billing process refer to the General Information of the Office of Finance web page located at <https://www.gpo.gov/how-to-work-with-us/vendors/how-to-get-paid>.

***Contractor's billing invoice must be itemized in accordance with the items in the "SCHEDULE OF PRICES."***

## SECTION 2. - SPECIFICATIONS

**SCOPE:** These specifications cover the production of blank and preprinted labels plus printer ribbons for Forensic Toxicology Drug Testing Laboratory.

**TITLE:** Labels and Printer Ribbons

### **ITEM 1: Extraction Label - Blank**

**FREQUENCY OF ORDERS:** 1 per year

**QUANTITY:** 156 rolls (3,000 labels per roll – 468,000 total labels)

**TRIM SIZE:** 1.45669" (37mm) x .590551(15mm), with 1/8" space between each label

**SPECIFICATIONS:** Blank thermal transfer label. Material is Transcode S-475 Polyolefin w/S-475 permanent acrylic adhesive and 1.0" core for Eltron with a 5.0" maximum outer diameter. Roll must fit in a Zebra 3842/GX430t printer. See Appendix A - Figure 1.

**PACKAGING:** 12 rolls, 36,000 labels per case.

**QUALITY CONTROL REQUIREMENTS:** See Appendix B.

### **ITEM 2: Morpher Label - Blank**

**FREQUENCY OF ORDERS:** 1

**QUANTITY:** 48 rolls (3,800 labels per roll – 182,400 total labels)

**TRIM SIZE:** 1.5" x .375", with 1/8" space between each label

**SPECIFICATIONS:** Blank thermal transfer label. Material is Transcode S-475 Polyolefin w/S-475 permanent acrylic adhesive and 1.0" core for Eltron with a 5.0" maximum outer diameter. Roll must fit in Godex label morpher/duplicator printer. See Appendix A - Figure 2.

**PACKAGING:** 12 rolls, 45,600 labels per case.

**QUALITY CONTROL REQUIREMENTS:** See Appendix C.

### **ITEM 3: Form/Folder Label - Blank**

**FREQUENCY OF ORDERS:** 1

**QUANTITY:** 12 rolls (2,400 labels per roll – 28,800 total labels)

**TRIM SIZE:** Outer Label Size: 2.875" x 1.5", includes 8 smaller internal labels sized: 1.4375" x .375"

**SPECIFICATIONS:** Blank thermal transfer label. Construction includes 8 smaller 1.4375" x .375" labels with a total outer label size of 2.875" x 1.5". Material is Transcode S-475 Polyolefin w/S-475 permanent acrylic adhesive and 3.0" core. See Appendix A - Figure 3.

**PACKAGING:** 4 rolls, 9,600 labels per case

**QUALITY CONTROL REQUIREMENTS:** See Appendix D.

#### **ITEM 4: Standard Tray Label - Printed**

FREQUENCY OF ORDERS: 4

QUANTITY: 2,750 sets (4 labels per set – 11,000 total label sets)

TRIM SIZE: 4.0" x 1.011"

SPECIFICATIONS: Printed in sets of 4. Delivered in loose sheets. One (1) sheet equals one set of 4 labels. Contractor may shrink wrap in suitable quantities.

PRINTING: Same text is printed per each set. See Appendix A - Figure 4

QUALITY CONTROL REQUIREMENTS: See Appendix E.

#### **ITEM 5: Folder Label - Printed**

FREQUENCY OF ORDERS: 4

QUANTITY: 1,500 sets (3 sheets per set - 4 labels per sheet – total of 12 labels per set).

TRIM SIZE: Total Label Size: 2.875" x 1.5", includes 8 internal labels sized: 1.4375" x 0.375"

SPECIFICATIONS: Printed barcode labels. Material is Transcode S-475 Polyolefin material w/S-475 permanent acrylic adhesive. Construction includes 8 smaller internal 1.4375" x 0.375" labels with a total outer labels size of 2.875" x 1.5". Each set includes 3 loose sheets with 4 labels per sheet, totaling 12 sequentially numbered labels per set (see example below). Batch numbering is continuous and will mirror Item 6. No missing or duplicate numbers. See Appendix A - Figure 5. *See below for kitting requirements for Item 5 and Item 6.*

PRINTING: Format sample "TR00-0001" or "TRBB-BBBB" - see Label Key Appendix A page 5.

Format Breakdown: "TR" (alpha – Tripler) prints on all labels = Batch number "BB-BBBB" - 6 digits that print sequentially throughout the year starting with 000002. Bar code symbology code 128.

The print order will include the starting batch number for each order.

**NOTE:** Human readable information will differ from the barcoded information. Human readable will include dashes while the barcode will have no dashes included. (i.e. Human readable: TR00-0002 | Barcode: TR000002)

Example of a set of 12 labels for Item 5:

- Each set includes 3 sheets
- Each sheet includes 4 large labels
- Each large label includes 8 smaller labels
- Sheet 1: numbered TR00-0002 through TR00-0005
- Sheet 2: numbered TR00-0006 through TR00-0009
- Sheet 3: numbered TR00-0010 through TR00-0013



This is one set Item 5 with 12 labels. (Item 6 would have mirrored sets TR00-0002-001 thru 150 through TR00-00013-001 thru 150 – see below for kitting requirements for Item 5 and Item 6)

QUALITY CONTROL REQUIREMENTS: See Appendix F.

### **ITEM 6: Specimen Processing Label - Printed**

FREQUENCY OF ORDERS: 4

QUANTITY: 1,500 sets (150 large labels per batch number set)

TRIM SIZE: Total Label Size: 1.5" x 1.5", includes 4 total internal labels - Size 1: 0.625" x 1.5" and Size 2: 0.292" x 1.5"

SPECIFICATIONS: Printed barcode labels – 1 wide. Material is Transcode S-475 Polyolefin material w/S-475 permanent acrylic adhesive. Construction: 4 smaller internal labels: (1) .625" x 1.5", (2) .292" x 1.5", (3) .292" x 1.5", (4) .292" x 1.5" with a total outer label size of 1.5" x 1.5". Each batch number set contains 150 sequentially numbered Specimen labels (each with 4 internal labels repeating the same batch and specimen number). Perforate between each label, fan-fold at every 6<sup>th</sup> label for a total of 150 large labels per set. Low specimen number on top right edge leading feeding to left to right. No missing or duplicate numbers allowed. See Appendix A - Figure 6. *See below for kitting requirements for Item 5 and Item 6.*

PRINTING: Each set prints with incrementing batch number and 150 sequentially numbered specimen labels (001-150). Format sample “TR000-002-001” or “TRBBB-BBB-SSS” - see Label Key Appendix A page 5.

Format Breakdown: “TR” (alpha – Tripler) prints on all labels = Batch number “BBB-BBB” - 6 digits that print sequentially throughout the year starting with 000002 = Specimen number “SSS” (001-150). Bar code symbology code 128. The specimen numbers “SSS” (001-150) start over for every batch number set.

The print order will include the starting batch number for each order.

**NOTE:** Human readable information will differ from the barcoded information. Human readable will include dashes while the barcode will have no dashes included. (i.e. Human readable: TR00-002-001 | Barcode: TR00002001).

QUALITY CONTROL REQUIREMENTS: See Sample Barcode Specifications - Appendix A - pages 6 to 8. See Appendix G.

### **SPECIAL PACKAGING/KITTING REQUIREMENTS FOR ITEM 5 AND 6:**

- Shrink wrap in sets of 12 batch numbers: 12 batch numbers for Item 6 (example: TR00-0002-001 to 150 through TR00-00013-001 to 150) shrink wrapped with every 12 batch numbers of Item 5 (example: 3 loose sheets numbered TR00-0002 through TR00-0013). The next shrink-wrapped package would be 12 of Item 6 (numbered TR00-0014-001 to 150 through TR00-00025-001 to 150) with 12 batch numbers of Item 5 (3 sheets numbered TR00-0014 through TR00-0025).
- Each shrink-wrapped package needs to be labeled with the 12 batch numbers within (which is the same for both Item 5 and 6).

### **ITEM 7: Batch LAN Label – Blank**

FREQUENCY OF ORDERS: 1

QUANTITY: 45,000 labels

TRIM SIZE: Total Label Size: 1.5" x 1.5", includes 4 internal labels: (1) .292" x 1.5", (2) .292" x 1.5", (3) .292" x 1.5", (4) .625" x 1.5"

**SPECIFICATIONS:** Blank thermal transfer label – 2 wide. Material is Transcode S-475 Polyolefin material w/S-475 permanent acrylic adhesive. Construction: 4 smaller labels: (1) .292" x 1.5", (2) .292" x 1.5", (3) .292" x 1.5", (4) .625" x 1.5" with a total outer label size of Set 1.5" x 1.5". Perforate vertically between every set, and horizontally halfway between each 2-wide set. Fan-fold at every 12th label (6 labels 2-wide for a total of 12 labels). 4,500 labels to a stack. See Appendix A - Figure 7.

**PACKAGING:** 4,500 labels to a stack, 2 stacks per case, 36,000 labels per case

**QUALITY CONTROL REQUIREMENTS:** See Appendix G.

**ITEM 8: QC Custom Piggy Back Label - Blank**

**FREQUENCY OF ORDERS:** 1

**QUANTITY:** 18 rolls (2,300 labels per roll, 41,400 total labels)

**TRIM SIZE:** Total Label Size: 2.90625" x 1.71875", includes 6 internal labels: (1) large label: 1.453" x 1.7185", and 5 small labels: (1) 1.453" x .40", (2) 1.453" x .348", (3) 1.453" x .348" (4) 1.453" x .348", (5) 1.453" x .274", with 1/8" space between each label.

**SPECIFICATIONS:** Blank thermal transfer piggy back label. Material is Transcode S-475 Polyolefin material w/S-475 permanent acrylic adhesive. Construction: 6 internal labels: includes 6 internal labels: (1) large label: 1.453" x 1.7185", and 5 small labels: (1) 1.453" x .40", (2) 1.453" x .348", (3) 1.453" x .348" (4) 1.453" x .348", (5) 1.453" x .274" with a total outer label size of 2.90625" x 1.71875", delivered in rolls with a 3.0" core and 1/8" space between each label. Must be able to be used on Zebra 110Xiii or 110XI4. See Appendix A – Figure 8.

**PACKAGING:** 6 rolls, 13,800 labels per case

**QUALITY CONTROL REQUIREMENTS:** See Appendix H

**ITEM 9: General Purpose Resin – Printer Ribbon (EXT label printer)**

**FREQUENCY OF ORDERS:** 1

**QUANTITY:** 24

**SIZE:** 2.5" (64mm) x 242' (74m)

**SPECIFICATIONS:** General Purpose Resin. Size: 2.5" (64mm) x 242' (74m), that will fit in a Zebra 3842/GX430t printer. See Appendix A – Figure L1.

**PACKAGING:** 12 per case

**ITEM 10: L3 Wax/Resin – Printer Ribbon (Morphers)**

**FREQUENCY OF ORDERS:** 1

**QUANTITY:** 96

**SIZE:** 2.13" x 984' (300m)

**SPECIFICATIONS:** L3 Wax/Resin, CSO. Size: 2.13" x 984' (300m), that will fit in a Godex label morpher/duplicator printer. See Appendix A – Figure L2.

**PACKAGING:** 24 per case.

**ITEM 11: Premium Wax/Resin – Printer Ribbon (Label Printers 1&2)**

FREQUENCY OF ORDERS: 1

QUANTITY: 120

SIZE: 3.54" x 1,476' (450m)

SPECIFICATIONS: Premium Wax/Resin Ribbon, Size: 3.54" x 1,476' (450m), that will be used on a Zebra 110XIII and 110XI4 printer.

PACKAGING: 24 per case.

**STOCK:** All labels shall consist of 4.0 mil white polyolefin material and adhere to the following characteristics:

1. The label adhesive shall be flexible enough to allow label position adjustments for minimum of 3 hours followed by permanent adhesion within 24 hours on paper, metal, plastic, and glass surfaces. The labels will be applied along the horizontal and vertical axis of tubes, sample bottles, and vials. The individual labels shall be easily peeled back and removed from the release liner. The labels shall be quickly removable and transferable from glass tube to glass or plastic vials during the extraction process without leaving adhesive residue on the glass or plastic tube or vial and without smudging the barcode or human readable characters to the point of non-readability. Adhesive must be made of permanent acrylic.
2. The labels shall not show any evidence of lifting or flagging at the edges after 3 days of exposure at room temperature, exposure to 20 minutes in an autoclave at 250 degrees Fahrenheit and 15 psi (total time of over 40 minutes in the autoclave), or after repeated removal and reapplication on glass or plastic test tubes during chemical extraction procedures.
3. The labels may be exposed to chemicals such as methanol, ethyl acetate, methylene chloride, iso-octane, iodopropane, iodomethane, isopropanol, 1-chlorobutane, dimethylsulfoxide, triethylamine, tetramethyl ammonium hydroxide, ammonium hydroxide, sodium hydroxide, potassium hydroxide, phosphoric acid, acetic acid, sulfuric acid, and hydrochloric acid. Labels should not fall off, or shrink under such exposure, and the print should not smear to the point of non-readability. This requirement also applies to exposure in the laboratory autoclave.
4. The labels must adhere to the glass tubes, plastic sample bottles, and glass vials when condensation occurs when removing tubes, vials, and bottles from freezer temperatures and refrigerated temperatures to room temperatures, and when glass tubes are placed in a heating apparatus in which steam condensation collects on the outer glass surface. Labels must not fall off from the plastic bottle or glass tube when condensation occurs due to thawing when removed from freezer and refrigerator.
5. Storage stability of rolled and fan folded labels shall be 12 to 18 months at 70 to 80 degrees Fahrenheit and 75% relative humidity after receipt of labels.
6. The release liner substrate shall be die cut to allow each label to be removed individually from the label roll. The gap between labels shall be 1/8 inch. Die cuts must be made by vendor for different label sizes and cuts. Once the die cut has been created the vendor must retain the die cut on their premise for future orders.

**IMPORTANT NOTE: No substitutions for material or adhesive allowed. Contractor may be required to provide documentation showing exact material and adhesive used for production. Labels and adhesive will be tested and must meet or exceed all quality control requirements listed in Appendix B-I.**

**GOVERNMENT TO FURNISH:** Form 2511 print order will be furnished to contractor via email. For printed labels the print order will include formula and format for sequencing data to be printed.

**CONTRACTOR TO FURNISH:** All materials and operations, other than those listed under "Government to Furnish," necessary to produce the product(s) in accordance with these specifications.

The contractor must be able provide digital means, methods and software necessary for the operation and support of the aforementioned professional publishing software (up to and including the most recent version) and shall possess a full complement of TrueType and Adobe fonts.

Immediately upon receipt and prior to image processing, the contractor shall be responsible for reviewing files on the furnished digital medium to ensure that such features as bleeds, register marks and file output settings have been provided to correctly generate the required output media. These prepress responsibilities, as well as the provision of necessary trapping, are to be provided at no additional cost to the Government.

**PACKING:** Pack in suitable shipping containers to ensure delivery without damage to contents.

**DELIVERY:** All expenses incidental to picking up and returning materials, and furnishing samples must be borne by the contractor. Also, refer to Articles 5 and 6, Supplemental Specifications, GPO Contract Terms, Publication 310.2, revised June 2001.

Orders will require the contractor to deliver f.o.b. destination.

All Shipments must be made via traceable means to:

Tripler Army Medical Center  
ATTN: MCHK-FT  
1 Jarret White Rd. Bldg. 40  
Tripler AMC, HI 96859

For each order placed, contractor must notify the ordering agency on the same day that the product ships/delivers via e-mail sent to Brittany A. Satovich at [brittany.a.satovich.civ@health.mil](mailto:brittany.a.satovich.civ@health.mil) and [compliance@gpo.gov](mailto:compliance@gpo.gov). The subject line of this message shall be "Distribution Notice for Jacket xxx-xxx, P.O. xxxxx, Print Order xxxxx". The notice must provide all applicable tracking numbers, shipping method, and Title. Contractor must be able to provide copies of all delivery, mailing, and shipping receipts upon agency request.

**SCHEDULE:** Adherence to this schedule must be maintained. Contractor must not start production of any job prior to receipt of the individual print order (GPO Form 2511).

No definite schedule for pickup of material/placement of orders can be predetermined.

The following schedule begins the workday after notification of the availability of print order and furnished material; the workday after notification will be the first workday of the schedule.

- Contractor must complete production of a single order and delivery within 20 workdays.
- Contractor is to ship/deliver by the date indicated on the print order.

The ship/deliver date indicated on the print order is the date products ordered for delivery f.o.b. destination must be delivered to the destinations specified.

Unscheduled material such as shipping documents, receipts or instructions, delivery lists, labels, etc., will be furnished with the order or shortly thereafter. In the event such information is not received in due time, the contractor will not be relieved of any responsibility in meeting the shipping schedule because of failure to request such information.

### **SECTION 3. - DETERMINATION OF AWARD**

The Government will determine the lowest Bid by applying the prices quoted in the "Schedule of Prices" to the following units of production which are the estimated requirements to produce one year's orders under this contract. These units do not constitute, nor are they to be construed as, a guarantee of the volume of work which may be ordered under this contract.

The following item designations correspond to those listed in the "Schedule of Prices".

**I.**

- 1. 156
- 2. 48
- 3. 12
- 4. 11,000
- 5. 6,000
- 6. 6,000
- 7. 45,000
- 8. 18
- 9. 24
- 10. 96
- 11. 120

## SECTION 4. - SCHEDULE OF PRICES

### **Bids offered are f.o.b. destination.**

Prices must include the cost of all required materials and operations for each item listed in accordance with these specifications.

Contractor must make an entry in each of the spaces provided. Bids submitted with any obliteration, revision, or alteration of the order and manner of submitting bids may be declared nonresponsive.

An entry of NC (No Charge) shall be entered if contractor intends to furnish individual items at no charge to the Government.

Bids submitted with NB (No Bid) or blank spaces for an item may be declared nonresponsive.

The Contracting Officer reserves the right to reject any offer that contains prices for individual items of production (whether or not such items are included in the Determination of Award) that are inconsistent or unrealistic in regard to other prices in the same offer or to GPO prices for the same operation if such action would be in the best interest of the Government.

Fractional parts of 1,000 shall be prorated at the “per 1,000” rate and fractional parts of 100 shall be prorated at the “per 100” rate.

**I. COMPLETE PRODUCT:** Prices bid shall include the cost of all required materials and operations necessary for the complete production and distribution of the product listed in accordance with these specifications.

1. ITEM 1: Extraction Label - Blank ..... \$ \_\_\_\_\_ per roll
2. ITEM 2: Morpher Label - Blank ..... \$ \_\_\_\_\_ per roll
3. ITEM 3: Form/Folder Label - Blank ..... \$ \_\_\_\_\_ per roll
4. ITEM 4: Standard Tray Label - Printed ..... \$ \_\_\_\_\_ per set
5. ITEM 5: Folder Label – Printed (includes special kitting) ..... \$ \_\_\_\_\_ per set
6. ITEM 6: Specimen Processing Label – Printed (includes special kitting) ..... \$ \_\_\_\_\_ per set
7. ITEM 7: Batch LAN Label - Blank ..... \$ \_\_\_\_\_ per label

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Initials

8. ITEM 8: Custom Piggy Back Label - Blank..... \$ \_\_\_\_\_ per roll
9. ITEM 9: General Purpose Resin – Printer Ribbon (EXT label printer)..... \$ \_\_\_\_\_ each
10. ITEM 10: L3 Wax/Resin – Printer Ribbon (Morphers) ..... \$ \_\_\_\_\_ each
11. ITEM 11: Premium Wax/Resin – Printer Ribbon (Label Printers 1 & 2)..... \$ \_\_\_\_\_ each

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Initials

**DISCOUNTS:** Discounts are offered for payment as follows: \_\_\_\_\_ percent, \_\_\_\_\_ calendar days. See Article 12 "Discounts" of Solicitation Provisions in GPO Contract Terms (Pub. 310.2).

**BID ACCEPTANCE PERIOD:** In compliance with the above, the undersigned agree, if this bid is accepted within \_\_\_\_\_ calendar days (60 calendar days unless a different period is inserted by the Firm) from the date for receipt of bids, to furnish the specified items at the price set opposite each item, delivered at the designated points(s), in exact accordance with specifications.

NOTE: Failure to provide a 60-day bid acceptance period may result in expiration of the bid prior to award.

**AMENDMENT(S):** Bidder hereby acknowledges amendment(s) number(ed) \_\_\_\_\_

**BIDDER NAME AND SIGNATURE:** Unless specific written exception is taken, the bidder, by signing and submitting a bid, agrees with and accepts responsibility for all certifications and representations as required by the solicitation and GPO Contract Terms – Publication 310.2. When responding by email, fill out and return one completed copy of all applicable pages that include the Jacket Number, Bid Price, Additional Rate, Discounts, Amendments, Bid Acceptance Period, and Bidder's Name and Signature, including signing and initialing where indicated (including all Appendix pages). Valid electronic signatures will be accepted in accordance with the Uniform Electronic Transactions Act, § 2. Electronic signatures must be verifiable of the person authorized by the company to sign bids.

Failure to sign the signature block below may result in the bid being declared non-responsive.

Firm \_\_\_\_\_  
(Contractor Name) \_\_\_\_\_ (GPO Contractor's Code)

\_\_\_\_\_ (Street Address)

\_\_\_\_\_ (City – State – Zip Code)

By \_\_\_\_\_  
(Printed Name, Signature, and Title of Person Authorized to Sign this Bid) \_\_\_\_\_ (Date)

\_\_\_\_\_ (Printed Name) \_\_\_\_\_ (Telephone Number)

\_\_\_\_\_ (Email) \_\_\_\_\_ (Fax Number)

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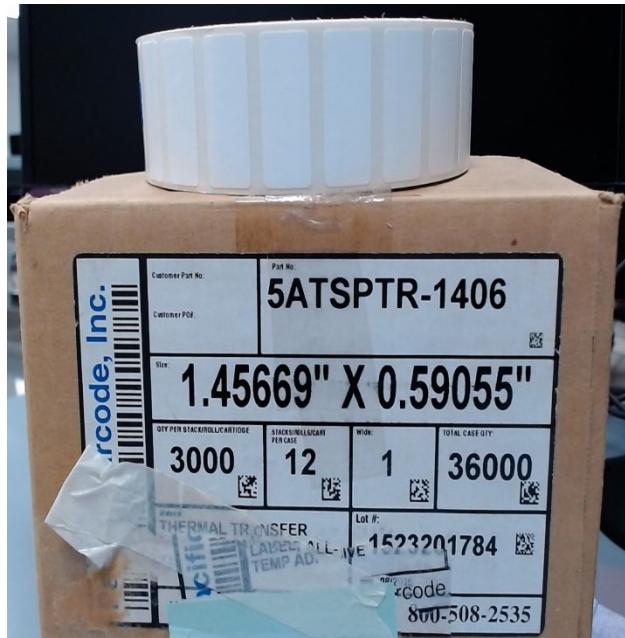
**THIS SECTION FOR GPO USE ONLY**

Certified by: \_\_\_\_\_ Date: \_\_\_\_\_ Contracting Officer: \_\_\_\_\_ Date: \_\_\_\_\_  
(Initials) \_\_\_\_\_ (Initials)

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## APPENDIX A

Item 1: Extraction Label – Blank (Figure 1)



Item 2: Morpher Label - Blank (Figure 2)



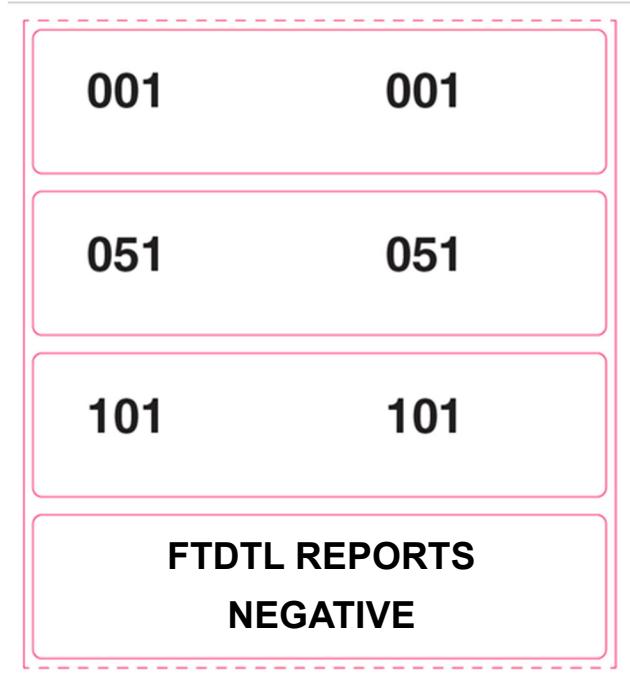
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Initials

Item 3: Folder/Form Label - Blank (Figure 3)



Item 4: Standard Tray Label – Printed (Figure 4)



Initials \_\_\_\_\_

Item 5: Folder Labels (Figure 5)



Item 6: Specimen Processing Label (Figure 6)



Item 7: Batch LAN- Blank Label (Figure 7)



Initials

Item 8: QC Custom Piggy Back Label (Figure 8)



Item 9: General Purpose Resin – Printer Ribbon (EXT label printer) (Figure L1)



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Initials

Item 10: L3 Wax/Resin – Printer Ribbon (Morphers) (Figure L2)



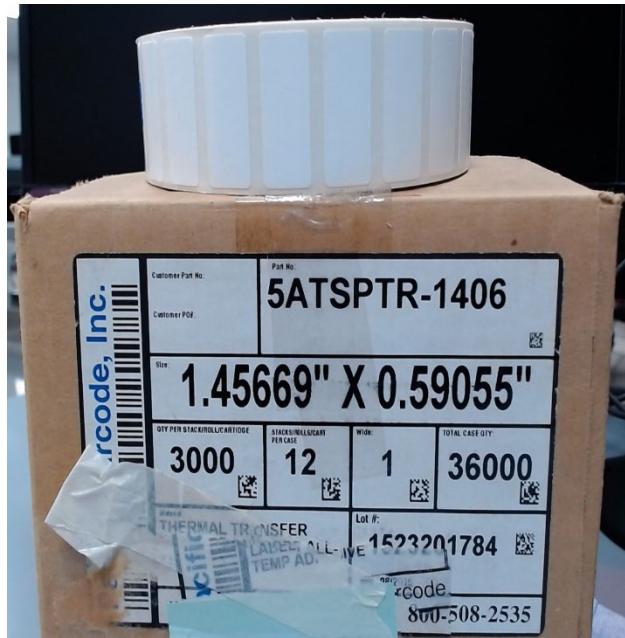
Item 5 and Item 6 Label Key:

Label Key		
	ITEM 5 (FOLDER)	ITEM 6 (SPECIMEN)
DESCRIPTION:	TR00-0002 TR= ALPHA 000002= BATCH #	TR000-002-001 TR= ALPHA 000002= BATCH # 001= SPECIMEN #
EXAMPLE:	TR00-0002 TR00-0002 TR00-0002 TR00-0002	TR000-002-001 TR000-002-002 TR000-002-002 TR000-002-001

Initials

## APPENDIX A

Item 1: Extraction Label – Blank (Figure 1)



Item 2: Morpher Label - Blank (Figure 2)



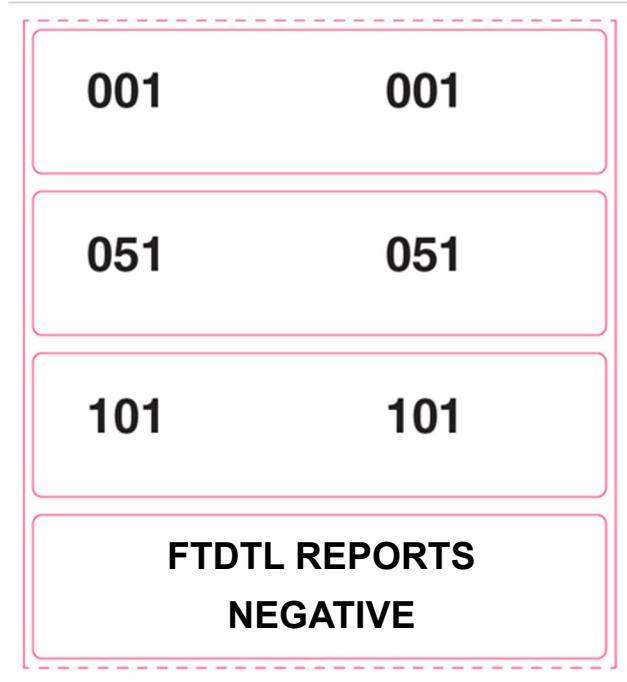
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Initials

Item 3: Folder/Form Label - Blank (Figure 3)



Item 4: Standard Tray Label – Printed (Figure 4)



Initials \_\_\_\_\_

Item 5: Folder Labels (Figure 5)



Item 6: Specimen Processing Label (Figure 6)



Item 7: Batch LAN- Blank Label (Figure 7)



Initials

Item 8: QC Custom Piggy Back Label (Figure 8)



Item 9: General Purpose Resin – Printer Ribbon (EXT label printer) (Figure L1)



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Initials

Item 10: L3 Wax/Resin – Printer Ribbon (Morphers) (Figure L2)



Item 5 and Item 6 Label Key:

Label Key		
	ITEM 5 (FOLDER)	ITEM 6 (SPECIMEN)
DESCRIPTION:	TR00-0002 TR= ALPHA 000002= BATCH #	TR000-002-001 TR= ALPHA 000002= BATCH # 001= SPECIMEN #
EXAMPLE:	TR00-0002 TR00-0002 TR00-0002 TR00-0002	TR000-002-001 TR000-002-002 TR000-002-003

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ISE (option)		
11. Types of consumables and approximate consumption		
	Name	Approximate daily consumption
	ISE buffer solution	Approx. 900 mL (in case of 1000 serum samples/day)
	ISE MID solution	Approx. 1300 mL (in case of 1000 serum samples/day)
	ISE REF solution	Approx. 175 mL (in case of 1000 serum samples/day)
	ISE Clean solution	Approx. 1 mL (in case of 1000 serum samples/day)

## 2.3.2 Sample Barcode Specifications

Analysis can be executed by using a barcode label as a sample ID. The following items define the barcode specifications used for identifying samples of the AU5800.

### Barcode type

Sample barcodes are comprised of the following types:

- NW-7
- CODE 39
- CODE 128, ISBT-CODE 128
- INT (Interleaved 2 of 5)

The system can read multiple barcodes when using a mixture of NW-7, CODE 39, CODE 128, or INT (interleaved 2 of 5).

The specifications of individual barcodes comply with the following standards.

Barcode	Compatible standard
NW-7	JIS-X-0506, USS-NW7
CODE 39	JIS-X-0503, USS-CODE 39
CODE 128	JIS-X-0504, USS-CODE 128
ISBT-CODE 128	ISBT 128
INT (Interleaved 2 of 5)	JIS-X-0502, USS-I2/5

### Character font

Barcode	Character font
NW-7	0 to 9
CODE 39	Alphanumeric, special characters
CODE 128	Alphanumeric, special characters
ISBT-CODE 128	Alphanumeric, special characters
INT (Interleaved 2 of 5)	0 to 9

**Precautions, Installation, and Specifications**

## 2.3 Major Specifications of the System

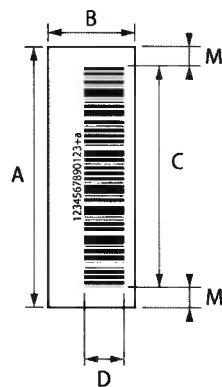
**Barcode digit number**

Maximum 26 digits

**Label size**

The size of sample barcode labels must follow the following specifications. (The unit is in millimeters.)

- Label length (A) < Sample tube length -12
- Label width (B): At least D+10mm, and not so wide that the label interferes with the barcode area.
- Barcode height (D)  $\geq$  10
- Top/bottom margin (M): shown below  
Other than CODE 128: 3 or more  
CODE 128: 10 times the X dimension or 2.54, whichever is larger, or more (quiet zone)
- Barcode area (C) = A - 2 x M

**Bar and space widths**

Bar and space widths must be as follows.

	<b>NB (narrow bar)</b>	<b>NS (narrow space)</b>	<b>WB (wide bar)</b>	<b>WS (wide space)</b>	<b>G (gap)</b>	<b>X<sup>(a)</sup> (size)</b>
Min	0.165 to 0.2 mm	NB to 1.25 NB	2.2 NB to 3.0 NB	2.2 NB to 3.0 NB	NB to 3.0 NB	0.191 or more
Max	0.2 to 0.5 mm		2.0 NB to 3.0 NB	2.0 NB to 3.0 NB	NB to 3.0 NB	

a. : In case of CODE128

Initials

## Barcode check character

A barcode can be selected from the following three methods:

- The check method is used from the following table.
- No check character is used.
- No check is performed although a check character is included.

Barcode	Check character method
NW-7	Least significant digit, MODULUS-16
CODE 39	Least significant digit, MODULUS-43
CODE 128, ISBT-CODE 128	Least significant digit, MODULUS-103
INT (Interleaved 2 of 5)	Least significant digit, MODULUS-10

## Barcode label print

Print barcode labels according to the following requirements to maintain readout accuracy:

- PCS value

If NB (narrow bar) width is between 0.165 and 0.50 mm the PCS value must be 0.60 or more.  
If NB (narrow bar) width is between 0.130 and 0.165 mm the PCS value must be 0.85 or more.

$$\text{PCS Value} = \frac{R_L - R_D}{R_L}$$

$R_L$  : white bar and margin light reflectance rate  
 $R_D$  : black bar dark reflectance rate

- CODE 128: MRD must be 37.5% or more.
- A void on a white bar (damage or print loss on a bar), ink spot (ink stain) and thin spot must meet the following requirements:
  - A spot diameter is 0.05 mm or less.
  - The void is 25% or less in a circular area with a diameter of 0.1 mm.
  - There is no marked blurring.

Initials

SECTION	REQUIREMENT	POTENTIAL PROBLEM	Test to perform	Label Material	Adhesive	Expected Result
QC, EXT	Current label size fits perfectly around the analyzer vials without overlapping & impeding any portion of the printed barcode.  REQUIRED SIZE: 1.45669" (37mm) x .590551(15mm)	Incorrect size of label may cause the labels to overlap, rendering it unreadable by the scanners.	Printed text / barcode			
EXT	MUST WITHSTAND:					
	Dry Heat up to 70°C					-Confirm Adhesiveness -Label Intact
QC, EXT	Label transfer at least 3 times, maintain adhesive	-no longer legible to accurately identify material content for accurate distribution and testing of material as well as potential use of using expired	visibly read/scan after test		reaffix label multiple times	-Confirm Adhesiveness -Label Intact
	Water bath up to 55°C, up to 3 times @ 15 min each					-Confirm Adhesiveness -Label Intact
QC, SP	Refrigeration 2-8°C; Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet	labels coming off--> LAX specimen(s)--> re-extract --> increased TAT -damaged label from normal daily use with freeze/thaw temperature changes.	visibly read/scan after test		Apply on tube and store in refer to see effectiveness of adhesive	-Confirm Adhesiveness -Label Intact
QC, SP	Water and urine (waterproof); Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet	labels coming off--> LAX specimen(s)--> re-extract --> increased TAT -damaged label from normal daily use with exposure to urine and freeze/thaw temperature changes.	visibly read/scan after test		Apply on glass tube and expose to water/urine to see effectiveness of adhesive	-Confirm Adhesiveness -Label Intact
	EXPOSURE TO SOLVENTS:					
	Concentrated Hydrochloric Acid					-Confirm Adhesiveness -Label Intact
	Acetic Acid					-Confirm Adhesiveness -Label Intact
	n-butyl chloride					-Confirm Adhesiveness -Label Intact
	hexane,					-Confirm Adhesiveness -Label Intact

QC, EXT	Acetonitrile	-damaged label from normal daily use with exposure to urine, chemicals.	Place labels on to glass/plastic tubes and expose to chemicals		Apply on tube and expose to solvent to see effectiveness of adhesive	-Confirm Adhesiveness -Label Intact
	Ammonium Hydroxide					-Confirm Adhesiveness -Label Intact
	Potassium Hydroxide					-Confirm Adhesiveness -Label Intact
QC, EXT	Methanol	-damaged label from normal daily use with exposure to chemicals			Apply on tube and expose to solvent to see effectiveness of adhesive	-Confirm Adhesiveness -Label Intact
	Ethyl Acetate					-Confirm Adhesiveness -Label Intact
	Dichloromethane					-Confirm Adhesiveness -Label Intact
QC	Isopropanol	-damaged label from normal daily use with exposure to chemicals			Apply on tube and expose to solvent to see effectiveness of adhesive	-Confirm Adhesiveness -Label Intact
QC, EXT	Adhesive must be able to withstand above conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off.	A label or adhesive that doesn't withstand above conditions may result in labels coming off--> LAX specimen(s)-> re-extract --> increased TAT	put through extraction process for each method			-Confirm Adhesiveness -Label Intact
EXT/SP/QC	Thermal transfer ribbon that we currently use holds up well & is made for our printers.  ZEBRA Part# 03200GS06407 (64mm x 74 m)	Must fit in our printers & be compatible with label type or we will not be able to aliquot as outlined in SOP	Print labels using current printer and ink			-Acceptable Material
GCMS	In the event that a label gets damaged during the extraction process & cannot be read by the MSD, GCMS tech has to create a new label. Printer uses the small labels that QC & SP used to have. These are not exposed to any special conditions.	all labels need to be readable by the MSD scanner for proper analysis.				Acceptable Material
GCMS	Label thickness must be thin enough to fit in the MSD barcode scanner (spinning scanner) and fit when being replaced in the tray.	this is an automated process so if label is too thick, it will not fit in the scanner & will cause errors & delays in shooting the batch. It may also cause errors when replacing the vial back into the tray if it doesn't fit perfectly--there is not extra room in the tray openings.				Acceptable Material
SP	Must withstand:					
SP, QC	Needs to be able to scan using the current handheld scanners and must be legible	If doesn't scan won't be entered into the computer which would null current process and if illegible techs can't verify if LAN printing out is correct	Scan using current scanners into computer			-Label intact
SP, QC	Size needs to fit over test tube without overlapping.	Incorrect size of label may cause the labels to overlap, rendering it unreadable by the scanners.		Place label on glass tube and see if it overlaps		-Acceptable Material

SP, QC	Needs to adhere to glass test tube. Must withstand wetness from urine and condensation from the fridge. If the tube gets wet it shouldn't fall off, smear or lift. It needs to be sticky enough to reapply/apply.	If it doesn't stick to glass tube it will affect current process. If gets wet and doesn't stick, results in taping excessive stickers to tubes, and possible LAX specimen(s)	visibly read/scan after test	Place label on glass tubes and see if sticks well  Perform pours with labels on test tube and see if labels fall off, smear or lifts.  Then place these in refrigerator and see if	-Acceptable Adhesiveness -Label Intact
SP, QC	Label thickness must be thin enough to fit in the extraction rack	May not fit the current racks and will have to discard and purchase new ones		Place label on tube and see if it fits in the extraction rack with ease	-Acceptable Material
QC	can transfer from test tube to paperwork without falling off paperwork. Can be cleanly removed from paperwork (without tear) and readhere without falling off paperwork.	damage forensic document when readjusting adhered label. Unnecessary time to fix document.	visibly read/scan after test	Place labels test tube, remove and adhere on paper then remove and readhere on paper	--Acceptable Adhesiveness -paperwork not ripped after adjusting label
QC	Able to write on labels without the writing becoming smeared (e.g. initials/date)	forensic pen/ink documentation smearing and no longer forensically legible. Identification of markings inaccurate	Write on labels with permanent ink pen and smudge with finger, expose to water, urine, solvents, and temperature conditions		7

SECTION	Test Number	REQUIREMENT	POTENTIAL PROBLEM	Test to perform	Expected Result
		Must withstand:		Printed text / barcode	
SP	1	Label transfer at least 3 times, maintain adhesive			-Acceptable Adhesiveness -Label Intact
	2	Refrigeration 2-8°C			-Acceptable Adhesiveness -Label Intact
	3	Freezer below 0°C (-18 to -23°C)			-Acceptable Adhesiveness -Label Intact
	4	Water and urine, waterproof			-Acceptable Adhesiveness -Label Intact
	5	Handling of up to 7 times			-Acceptable Adhesiveness -Label Intact
	6	Thaw and re-freeze processes			-Acceptable Adhesiveness -Label Intact
SP	7	Adhesive must be able to withstand above conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet. Needs to be sticky enough to adhere to paper for long periods of time (>1yr). Sticky enough but not too sticky that label rips the paper	A label or adhesive that doesn't withstand above conditions may result in labels coming off--> LAX specimen(s)-> re-extract --> increased TAT	Apply on paper and try removing labels multiple times to see effectiveness of adhesive and if paper rips	-Acceptable Adhesiveness -Label Intact
SP	8	Needs to be able to scan using the current handheld scanners and still be legible. Needs to be able to scan/morph, legible, and durable (will it be readable and sticky after 1-3yrs)	If doesn't scan won't be entered into the computer which would null current process and if illegible techs can't verify if info printing out correct	Scan using current scanners into computer and on morphers	-Label Intact

SP	9	Thermal transfer ribbon that we currently use holds up well & is made for our printers.  ZEBRA Part# 03200GS06407 (64mm x 74 m)	Must fit in our printers & be compatible with label type	Print labels using current printer and ink	-Acceptable Material
SP	10	Size needs to fit within pre-determined field/blocks on paper without going into the other block	Incorrect size of label may cause the labels to go into the other blocks causing incorrect scanning	Place label on paper and see if fits nicely in blocks and if somewhat easy to remove without ripping the paper	-Acceptable Material
SP	11	Needs to adhere to plastic bottle and cap, the outside of the package container, as well as extraction rack.		Place label on plastic bottle and cap, the outside of the package container, as well as extraction rack, and see if sticks well	-Acceptable Material -Label Intact
SP	12	Must withstand wetness from urine and condensation from the fridge. If the plastic bottle or box gets wet it shouldn't fall off, smear or lift. It needs to be sticky enough to reapply/apply.	If gets wet and doesn't stick, results in taping excessive stickers to bottles and box, and possible LAX specimen(s). Also possible false positive	Label plastic bottle and cap, the outside of the package container, as well as extraction rack, and place in refrigerator and freezer see if labels fall off  See if labels fall off, smear or lifts after removing from fridge and freezer	-Acceptable Adhesiveness -Label Intact
Screen	13	Dimensions	May not fit on Assay Review sheet form nicely in the designated area	Adjust the Assay Review form to fit label	Label doesn't cover anything on form
Screen	14	Dimensions	May not fit on Assay Review sheet form nicely in the designated area	Find a label that will fit Assay Review form	Label doesn't cover anything on form

SECTION	Test Number	REQUIREMENT	POTENTIAL PROBLEM	Test to perform	Expected Result
				Printed text / barcode	
SP		Must withstand:			
	1	Label transfer at least 3 times, maintain adhesive			-Acceptable Adhesiveness -Label Intact
	2	Water and urine, waterproof			-Acceptable Adhesiveness -Label Intact
	3	Handling of up to 7 times			-Acceptable Adhesiveness -Label Intact
SP	4	Adhesive must be able to withstand above conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet. Needs to be sticky enough to adhere to paper for long periods of time (>1yr). Sticky enough but not too sticky that label rips the paper	A label or adhesive that doesn't withstand above conditions may result in labels coming off--> LAX specimen(s)--> re-extract --> increased TAT	Apply on paper and try removing labels multiple times to see effectiveness of adhesive and if paper rips	-Acceptable Adhesiveness -Label Intact
SP	5	Needs to be able to scan using the current handheld scanners and legible. Needs to be able to scan/morph, legible, and durable (will it be readable after 1-3yrs)	If doesn't scan won't be entered into the computer which would null current process and if illegible techs can't verify if info printing out correct	Scan using current scanners into computer and on morphers	-Label Intact
SP	6	Thermal transfer ribbon that we currently use holds up well & is made for our printers.  ZEBRA Part# DYNWR-354450 (3.54" x 450M)	Must fit in our printers & be compatible with label type	Print labels using current printer and ink	-Acceptable Material
SP	7	Size needs to fit upper side of 2624 and middle of 2624 without being too large that it blocks unit info		Place label on paper and see if fits nicely in the corner and if somewhat easy to remove without ripping the paper	-Acceptable Material

Initials

SP	8	Must withstand wetness from urine and condensation from the fridge. If the plastic bottle, box, or paper gets wet it shouldn't fall off, smear or lift. It needs to be sticky enough to reapply/apply.	If gets wet and doesn't stick, may cause the mislabeling of forms and incorrect forms being associated with different specimens. Difficulty in locating forms. If gets wet and doesn't stick, results in taping excessive stickers to bottles and box.	Label form and wet paper to see if labels fall off, smears or lifts.  Label plastic bottle and cap, the outside of the package container, place in refrigerator and see if labels fall off  See if labels fall off, smear or lifts after removing from fridge	-Acceptable Adhesiveness -Label Intact
SP	9	Needs to adhere to plastic bottle and cap, and the outside of the package container		Place label on plastic bottle and cap, the outside of the package container, and see if sticks well	-Acceptable Adhesiveness -Label Intact

Initials

SECTION	Test Number	REQUIREMENT	POTENTIAL PROBLEM	Test to perform	Expected Result
				Printed text / barcode	
SP		Must withstand:			
	1	Label transfer at least 3 times, maintain adhesive			-Acceptable Adhesiveness -Label Intact
	2	Water and urine, waterproof			-Acceptable Adhesiveness -Label Intact
	3	Handling of up to 4 times			-Acceptable Adhesiveness -Label Intact
SP	4	Adhesive must be able to withstand above conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet or rips paper.	May fall off of trays and cause mislabeling and then premature dumping of specimens	Apply on paper and trays and try removing labels multiple times to see effectiveness of adhesive and if paper rips	-Acceptable Adhesiveness -Label Intact
SP	5	Size needs to fit in on the trays and folder without being too big		Place label on tray, folder and paper see if fits nicely and if somewhat easy to remove without ripping the paper	-Acceptable Adhesiveness -Acceptable Material -Label Intact
SP	6	Must withstand wetness from urine. If the paper gets wet it shouldn't fall off, smear or lift. It needs to be sticky enough to reapply/apply.	May fall off of trays and cause mislabeling and then premature dumping of specimens	Place on paper, tray and folder see if when gets wet if labels fall off, smears or lifts	-Acceptable Adhesiveness -Label Intact
SP	7	Must be able to apply a folder label on top and this tray label shouldn't rip when folder labels adhered to the top	Folder labels may fall off and same as above	Place folder label on top and see if sticky.  Wet tray label and see if folder label falls off	-Acceptable Adhesiveness -Acceptable Material -Label Intact

Initials

<u>SECTION</u>	<u>Test Number</u>	<u>REQUIREMENT</u>	<u>POTENTIAL PROBLEM</u>	<u>Test to perform</u>	<u>Expected Result</u>
SP		Must withstand:		Printed text / barcode	
	1	Label transfer at least 3 times, maintain adhesive			-Acceptable Adhesiveness -Label Intact
	2	Water and urine, waterproof			-Acceptable Adhesiveness -Label Intact
	3	Handling of up to 7 times			-Acceptable Adhesiveness -Label Intact
SP	4	Adhesive must be able to withstand above conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet. Needs to be sticky enough to adhere to paper for long periods of time (>1yr). Sticky enough but not too sticky that label rips the paper	A label or adhesive that doesn't withstand above conditions may result in labels coming off--> LAX specimen(s)--> re-extract --> increased TAT	Apply on paper and try removing labels multiple times to see effectiveness of adhesive and if paper rips	-Acceptable Adhesiveness -Label Intact
SP	5	Needs to be able to scan using the current handheld scanners and legible. Needs to be able to scan/morph, legible, and durable (will it be readable after 1-3yrs)	If doesn't scan won't be entered into the computer which would null current process and if illegible techs can't verify if info printing out correct	Scan using current scanners into computer and on morphers	-Label Intact
SP	6	Size needs to fit within fields without overlapping.	Incorrect size of label may cause the labels to go into the other blocks causing incorrect scanning	Place label on paper and see if fits nicely in blocks and if somewhat easy to remove without ripping the paper	-Acceptable Material
SP	7	Must withstand wetness from urine. If the folder gets wet the label shouldn't fall off, smear or lift. It needs to be sticky enough to reapply/apply.	If gets wet and doesn't stick, may cause the mislabeling of folder and incorrect folders being associated with different forms.	Label manila folders and see if labels fall off  If labels get wet see if fall off, smear or lifts	-Acceptable Adhesiveness -Label Intact

<u>SECTION</u>	<u>Test Number</u>	<u>REQUIREMENT</u>	<u>POTENTIAL PROBLEM</u>	<u>Test to perform</u>			<u>Expected Result</u>
SP		Must withstand:		Printed text / barcode	Label Material	Adhesive	
	1	Label transfer at least 3 times, maintain adhesive					-Acceptable Adhesiveness -Label Intact
QC, SP	2	Refrigeration 2-8°C					-Acceptable Adhesiveness -Label Intact
QC, SP	3	Freezer below 0°C (-18 to -23 °C)					-Acceptable Adhesiveness -Label Intact
QC, SP	4	Water and urine, waterproof					-Acceptable Adhesiveness -Label Intact
QC, SP	5	Handling of up to 7 times					-Acceptable Adhesiveness -Label Intact
QC, SP	6	Thaw and re-freeze processes					-Acceptable Adhesiveness -Label Intact
QC, SP	7	Adhesive must be able to withstand above conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet. Needs to be sticky enough to adhere to paper for long periods of time (>1yr). Sticky enough but not too sticky that label rips the paper	A label or adhesive that doesn't withstand above conditions may result in labels coming off--> LAX specimen(s)--> re-extract --> increased TAT	Apply on plastic bottle and form and try removing labels multiple times to see effectiveness of adhesive			-Acceptable Adhesiveness -Label Intact
QC, SP (*Screening, see below for similar concern)	8	Needs to be able to scan using the current handheld scanners and legible. Needs to be able to scan/morph.	If doesn't scan won't be entered into the computer which would null current process and if illegible techs can't verify if LAN printing out is correct	Scan using current scanners into computer. Also morph using morphers.			-Label Intact
QC, SP (*Screening, see below for similar concern)	9	Size needs to fit over plastic test tube without overlapping; can't cover entire tube	Incorrect size of label may cause the labels to overlap, rendering it unreadable by the scanners.	Place label on tube and see if it overlaps			-Acceptable Material
QC, SP (*Screening, see below for similar concern)	10	Needs to adhere to plastic polypropylene test tube, plastic bottle and cap and paper. Must withstand wetness from urine and condensation from the fridge. If the tube or bottle gets wet it shouldn't fall off, smear or lift. It needs to be sticky enough to reapply/apply.  Shouldn't be too thick where the tube with the LAN can't be inserted in the batch rack	If it doesn't stick to tube it will affect current process. If gets wet and doesn't stick, results in taping excessive stickers to tubes, and possible LAX specimen(s). Also may result in false positive	Place label on tubes, bottles and caps, and paper and see if sticks well  Perform pours with labels on test tube and bottles see if labels fall off, smear or lifts. Does it fit in rack  Then place these in refrigerator and see if labels fall off. Then in freezer. Then thaw and freeze			-Acceptable Adhesiveness -Acceptable Material -Label Intact

QC, SP (*Screening, see below for similar concern)	11	Size needs to fit within pre-determined field/blocks on paper without going into the other block. Needs to be durable (will it be readable and sticky after 1-3yrs)	Incorrect size of label may cause the labels to go into the other blocks causing incorrect scanning and false positive	Place label on paper and see if fits nicely in blocks and if somewhat easy to remove without ripping the paper  Wet paper, does label stick, smear, fall off, flag			-Acceptable Material
QC,*Screen	12	Dimensions	May cover the entire tube, technician may not see the sample volume	Place label on tube			Should not cover entire length of tube and should not overlap
*Screen	13	Adhesive	May not stick on tube when semi-wet	Have SP tech label tubes that are somewhat wet and then transfer to Screening			Label adheres to plastic tube at all times, from beginning to end of day
*Screen	14	Adhesive	May not stay on tube when refrigerated	Refrigerate tube with labels			Label continues to adhere to tubes after removing from fridge and sitting out a day
*Screen	15	Top Coat	May not scan barcode for barcode error fixes	Print barcode on label and scan with scanner			Labels are scannable and barcode info. correct
*Screen	16	Top Coat	May be easily damaged/smeared by abrasions, moisture, wear and tear	Have SP or QC print barcode on label with current ink supply and see if it dries fast			Labels are scannable and barcode info. correct
QC,Screen	17	Compatible	May not be read by AU5800 for some unknown reason	Calibrate and run a batch or non-chain with new labels			Labels are scannable and barcode info. correct with no barcode read errors from the analyzer
QC,*Screen	18	Thickness	If to thick, may be difficult to place labeled tube into Screening rack for SP techs	Ask SP to place labeled tubes into Screening racks			SP not struggling when placing tube in screening rack
Screen	19	Thickness	If to thick, may be difficult to remove tube from Screening rack	Screening tech will manually remove tubes from Screening racks			Screening tech not struggling when removing tube from screening rack

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SECTION	Test Number	REQUIREMENT	POTENTIAL PROBLEM	Test to perform			Expected Result
QC	1	Must withstand: Label transfer at least 3 times, maintain adhesive	adhesive does not remove from tube cleanly with sufficient adhesive remaining to relabel on tube or paperwork -label adhesiveness decreased after readusting and falls off in temperature changes. Need to discard material and this incurs unnecessary cost.	Printed text / barcode visually read and scan after testing	Label Material does not tear	Adhesive Apply on tube and try removing labels multiple times to see effectiveness of adhesive	should still be sticky after removing multiple times, not tear, print legible and able to scan
QC	2	Water and urine (waterproof)	labels coming off: LAX specimen(s)--> re-extract --> increased TAT and control material mis-identification -illegible print causing control material misidentification	visually read and scan after testing		expose labelled items to water and urine conditions	should still be sticky after removing multiple times and not break or rip paper
QC	3	Must withstand: refrigeration 2-6 degC	labels coming off: LAX specimen(s)--> re-extract --> increased TAT and control material mis-identification -illegible print causing control material misidentification	visually read and scan after testing		expose labelled items to refer conditions	Adhesive must be able to withstand conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet.
QC	4	Must withstand: freezer -10 - -40 degC	labels coming off: LAX specimen(s)--> re-extract --> increased TAT and control material mis-identification -illegible print causing control material misidentification	visually read and scan after testing		expose labelled items to freezer conditions	Adhesive must be able to withstand conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet.
QC	5	Must withstand: repeated freeze/thaw conditions	labels coming off: LAX specimen(s)--> re-extract --> increased TAT and control material mis-identification -illegible print causing control material misidentification	visually read and scan after testing		expose labelled tubes to refer and room temp multiple times	Adhesive must be able to withstand conditions. Sticky enough to be transferred multiple times, but not so sticky that label breaks when trying to peel it off or falls off if it gets wet.
QC	6	scan using the current handheld scanners and legible.	manual entry decreasing accuracy into database and label reprints	Scan using current scanners into computer.			Should scan/read exactly what's on the label.
QC	7	Thermal transfer ribbon that we currently use holds up well & is made for our printers.  ZEBRA Part#	Purchase new equipment and incur unnecessary cost.	Print labels using current printer and ink			Ensure it prints on the printer and ribbon/ink adheres nicely to label. Shouldn't smear or rub off
QC	8	Needs to adhere to plastic polypropylene test tube and current urine collection container.	inaccurate identification of sample	Place label on tubes, and see if sticks well  Perform pours with labels on test tube and see if labels fall off, smear or lifts. Does it fit in rack			Should adhere well to the plastic tube and not flag, fall off or smear when wet.  When applied to test tube, tube should fit nicely in rack

QC	9	Adhere to paper and on current specimen labels from collection base units		visually read and scan after testing		apply on paper and specimen bottle label (on bottle)	should adhere to paper and bottle label without falling off
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