

Update on 1D and 2D Bar Coding for the Laboratory

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Disclosures

- Financial
 - Paid Faculty for American Medical Informatics Association Clinical Informatics Board Review Course
 - Employee of Children's Healthcare of Atlanta
- Other disclosures
 - **Secretary for the CLSI AUTO14 Document Development Committee – Two-dimensional barcoding for the laboratory (AP and CP)**
 - Association of Molecular Pathology → Informatics Subdivision Chair, Board of Directors, Executive Committee
 - College of American Pathologists → Member of Informatics Committee



Objectives

- By the end of this presentation, the participant should be able to:
 - Understand the advantages and disadvantages of linear vs. 2D bar codes
 - Describe the danger associated with any improperly configured bar code systems
 - Know the elements required to properly implement linear and 2D bar code systems
 - Describe current barcoding standards and gaps in standards



How this all got started...

- It's 2009, I get a call from the point of care staff
- Our point of care glucose analyzers had read the **wrong number** from about 10 patient armband bar codes over the weekend
- Caught by point of care middleware
 - Patient to whom wrong number belonged not currently admitted to hospital



How this all got started...

- But what if the patient had been admitted?
 - **The wrong glucose value would have flown right into the wrong patient's chart**
- Are we still at risk of having this happen again with potentially devastating consequences?
 - **YES**



How this all got started...

- Worst case scenario
 - High glucose level belongs to patient A
 - Point of care glucometer misreads bar code
 - Misread bar code number belongs to patient B
 - Patient B, also diabetic, currently admitted to same unit
 - High glucose level seen in EHR by physician → prescribes insulin for patient B and starts to come to the unit
 - By the time the physician arrives, the patient is comatose

Reports received by FDA

From 1997 - 2009, FDA received 13 reports of death associated with GDH-PQQ glucose test strips in which there was interference from maltose or other non-glucose sugars. The deaths occurred in healthcare facilities. Some reports indicated that serious patient injury, such as low blood glucose (hypoglycemia), confusion, neurologic deterioration, too little oxygen in the tissues (severe hypoxia), brain damage and coma, occurred prior to death.

FDA is working with manufacturers to resolve the problems with GDH-PQQ glucose test strips, and is continuing to monitor adverse events associated with these products.



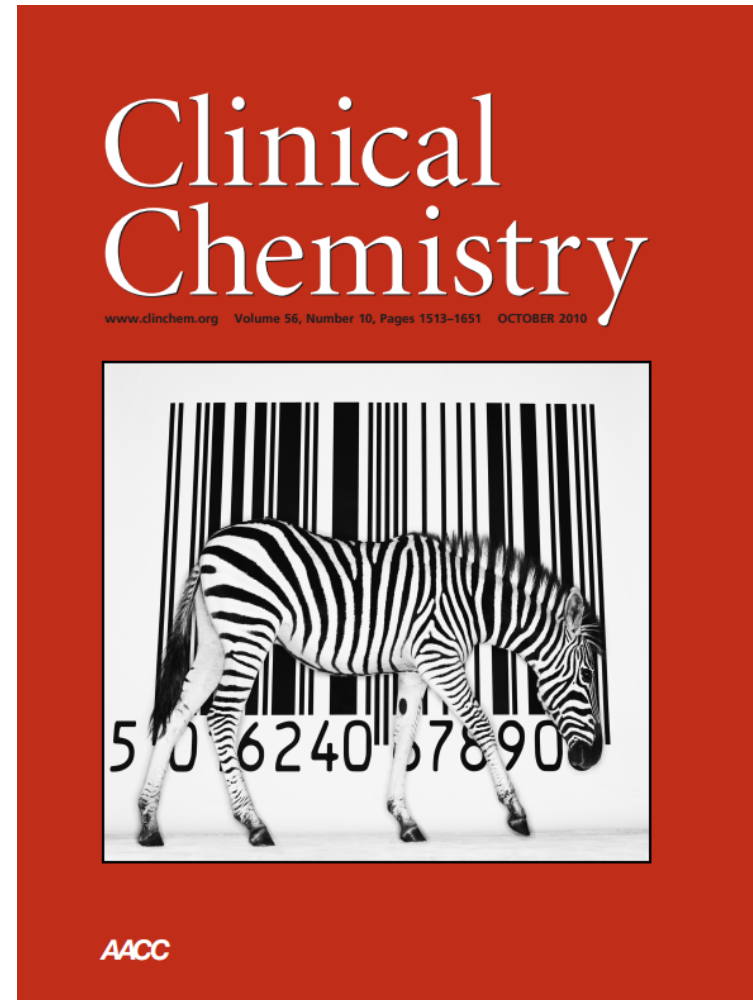
Moments in my career I'll always remember...



What did we do?

- Risk management
- Improved our implementation of bar codes
- Published our data
- **No recurrences**
- We start working on new barcoding standard with CLSI (long process)
- I transition to a new facility in 2015, and then...

Stay tuned for
end of talk



Bar Codes

- Graphical machine-readable representation of alphanumeric characters
- Can be read (decoded) by a bar code reader (scanner)
- Advantages
 - Reduces / eliminates manual typing errors
 - Improves speed of data entry
- Strong recommendations supported by guidelines: ensure that the human-readable version of the encoded data is always printed next to the bar code



Linear Bar Codes

- a.k.a. one-dimensional
- bars and spaces
- Read (decoded) in 1 dimension
- Most commonly used bar code type in laboratories
- Different symbologies available



Linear Bar Codes

Code 39	 0123456789
Code 128A	 0123456789
Code 128B	 0123456789
Code 128C	 0123456789



Code 128 Structure



Bar Code module	smallest individual element in a bar code
X-Dimension	The width of a single bar code module Typically represented in mil Determines the bar code's overall density
Mil	0.001 inch (1/1000 inch) 0.0254 mm

<http://www.adams1.com/128table.html>



Definitions

- **Check character**

- a character that is added to the end of a block of transmitted data and used to check the accuracy of the transmission

- **Checksum**

- A checksum is a value used to verify the integrity of a [file](#) or a data transfer. In other words, it is a sum that checks the validity of data. Checksums are typically used to compare two sets of data to make sure they are the same. A checksum can be computed in many different ways, using different [algorithms](#). For example, a basic checksum may simply be the number of [bytes](#) in a file.



Code 128C – Check chr



Barcode Content	Check Character	Modules (11 modules for start character; 11 modules for each 2-digit number in sequence including the check character; and 13 modules for the stop character)									
0123456789											
		Start Chr C	01	23	45	67	89				Stop chr

$$\begin{aligned}
 \text{Checksum} &= 105 + (XX_1 * 1) + (XX_2 * 2) + \dots + (XX_n * n) \\
 &= 105 + (01 * 1) + (23 * 2) + (45 * 3) + (67 * 4) + (89 * 5) = 1000
 \end{aligned}$$

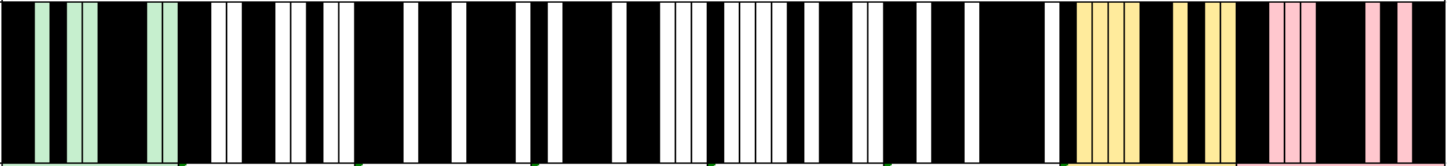
$$\text{CheckChr} = \text{Modulus} \left(\frac{\text{Checksum}}{103} \right) = \text{Modulus} \left(\frac{1000}{103} \right) = 73$$

There are only 103 possible check characters (0 through 102).

That's not a lot.

Printing

Here is the encoded string:

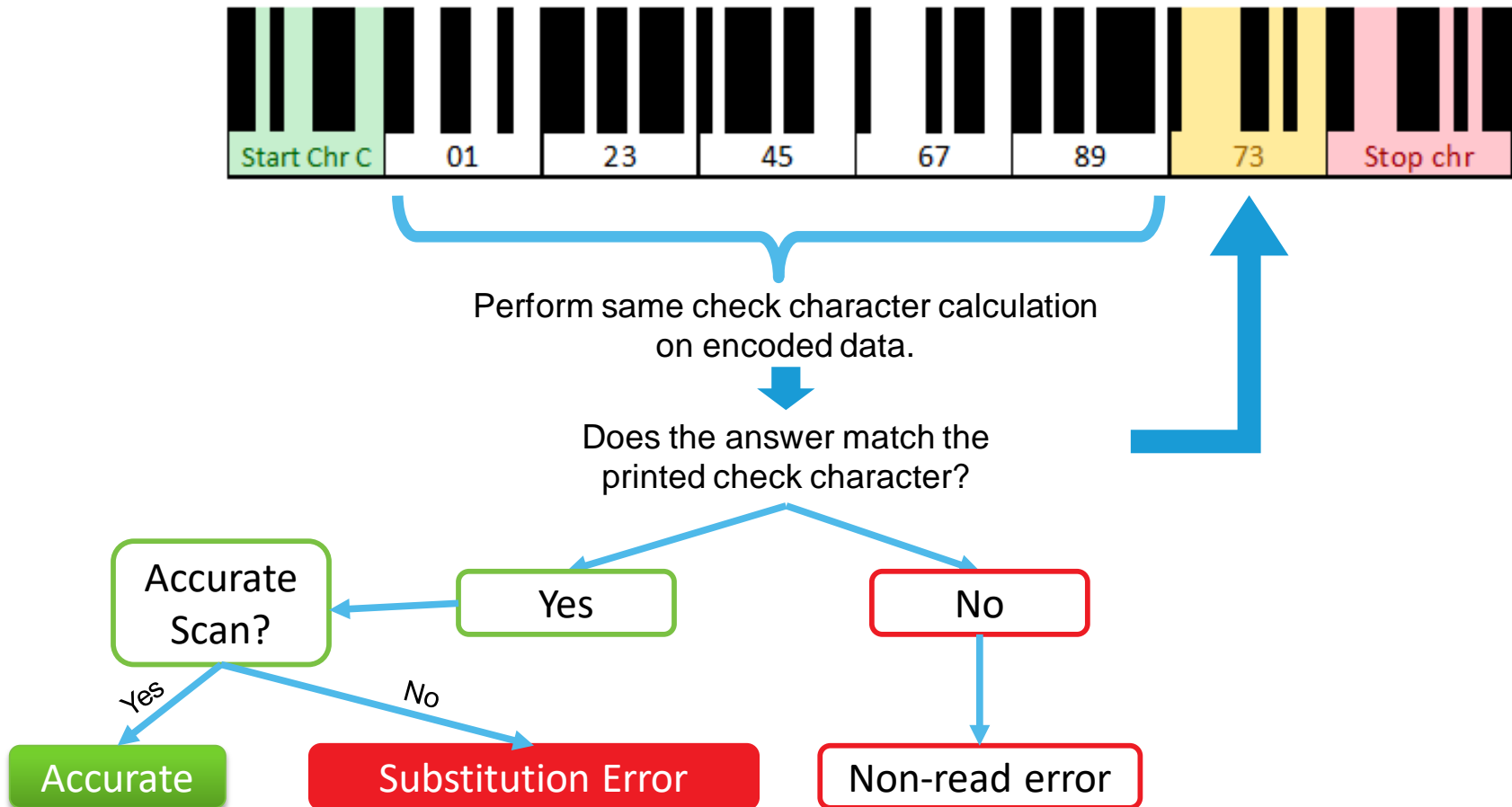
Barcode Content	Check Character	Modules (11 modules for start character; 11 modules for each 2-digit number in sequence including the check character; and 13 modules for the stop character)									
0123456789	73										
		Start Chr C	01	23	45	67	89	73	Stop chr		

Here is what the printer prints:



Scanning

Here is how the scanner decodes the bar code:



CLSI AUTO-02

- First effort outside of blood bank to establish barcoding standards for laboratories
 - To facilitate automation
 - Only addresses clinical laboratory specimens
 - Does not address anatomic pathology specimens
 - Does not address patient armband bar codes
- Deprecates the use of the following bar codes as of December 31, 2003:
 - Codabar, NW7, Interleaved 2 of 5 (none have check characters)
 - Code 39 (check character is optional)



CLSI AUTO-02

- Establishes Code 128 as the acceptable bar code symbology
 - Required integral check character
 - Accommodates almost all ASCII characters
 - Code 128C takes up less space (double-density)
- Establishes specs for
 - Bar Code mil size
 - Quiet zone size
 - Label placement on tube
 - Orientation of label and bar code on tube
 - Opacity of label



ISBT 128 Standard

- Bar Code labeling standard for medical products of human origin (e.g., blood products)
- Began development in 1996
- Code 128 approved as linear symbology
- DataMatrix is the approved 2D symbology
- RFID also allowed if meets criteria



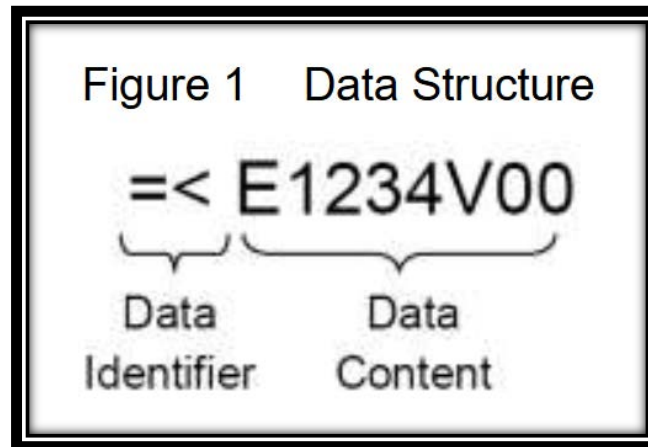
ISBT 128 Standard

- In addition to printer specifications, ISBT 128 sets standards for:
 - Multiple bar codes, each with specified data identifiers, structures and content
 - Scanner resolution requirements
 - Information system software requirements
 - Requires printers to be able to accommodate the required X-dimension

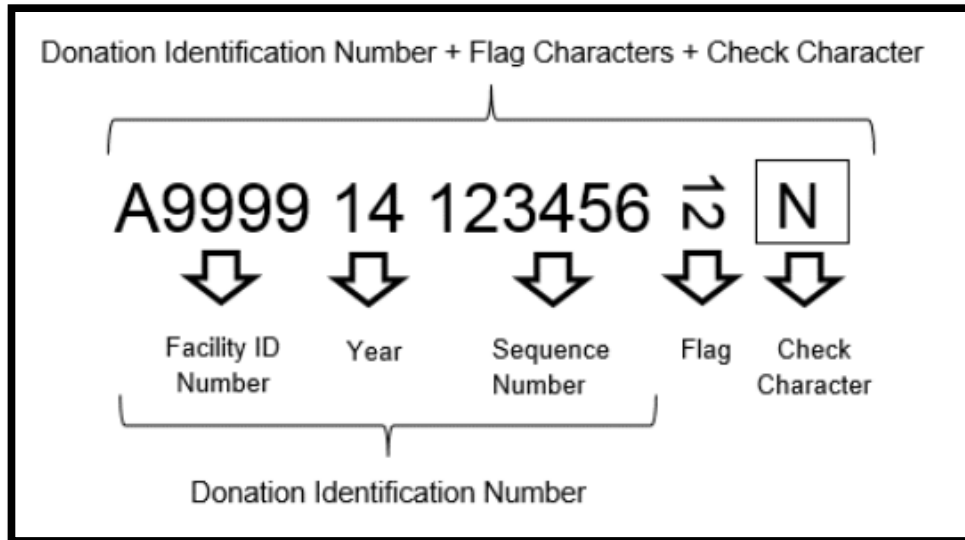


ISBT 128 Structure

- Data structure = Data Identifier + Data Content
 - Data Identifier
 - 2 to 3 character prefix which identifies the data structure
 - Example: =< equals **Product Code**
 - Data content
 - Data that provides the information to be conveyed



ISBT 128



Structure: `=;appppvvvvvvvvvvvvvvvv`

Element	Length	Type
=	1	data identifier, first character
;	1	data identifier, second character
a	1	alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A–N, P–Z, 0–9}, second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future.
vvvvvvvvvvvvvvvv	16	numeric {0–9}

- What's actually encoded:

(Start Chr) ;=A99991412345612 (Check Chr) (Stop Chr)



ISBT 128

In order to accurately interpret information from an ISBT 128 bar code, application software shall carry out the following two steps before interpreting the data values:

1. Analyze the data identifier characters to ensure that the bar code entered is of the correct type;
2. Verify that the length and format of the data content match that defined for the corresponding data structure.

Failure to carry out these checks could lead to incorrect assignment of critical information.

Stringency of specification is likely the reason why, to date, no errors have been reported with the use of Code 128 in this setting

ISBT 128 Standard Technical Specification version 5.9.0 (March 2018). ICCBBA.
<https://www.iccbba.org/uploads/71/45/7145f0c5b069c2e0a8de13a939ca3ad8/ST-001-ISBT-128-Standard-Technical-Specification-v5.9.0.pdf>. Accessed May 22, 2018.

Positive Patient ID for transfusions

- Unique product ID requires both of these bar codes
 - **Unit number** (a.k.a. Donor Identification Number)
 - Uniquely identifies the product donation event
 - One donation = one unit number
 - **Product Code**
 - For the donated product, the product code uniquely identifies the original product from each split product and from each derivative product
 - If you split/alter a product into three components, each of the components will have a unique product code which is different from the original product code



Positive Patient ID (PPID) for transfusions

- Matching a product to a patient
 - Products should be checked to ensure that they have been ISSUED to the patient
 - Blood Bank LIS sends product information to PPID system upon ISSUING from the blood bank
 - If product has not been altered since it was donated
 - Unit number of the product to be transfused is sufficient
 - Both unit number and product code are recommended
 - If a product has been split or altered in any way
 - For each product to be transfused, **BOTH unit number and product code** must match the product **issued** to the patient
 - Two splits of the same product
 - 1 irradiated, 1 not irradiated
 - 1 larger volume, 1 smaller volume



So what can go wrong?

- Non-ISBT 128 patient armband bar codes
- 2009: Examples of bar codes that we pulled off of patients (slightly altered to protect PHI)



- Problems?
 - Post-printing damage
 - Print quality
 - These bars sure seem skinny...



Bar Code Resolution

- Printed bar code resolution
 - Encoded content for Code 128C
 - 12 numeric characters = 90 total modules
 - **13 mm** total width (0.511811 inches or 511 mils)
 - X-dimension = 5.67 mil per module
- Scanner bar code resolution
 - Manufacturer told us that minimum resolution was 7.5 mil
 - Ironically, minimum mil size for CLSI AUTOA2 also is 7.5 mil
 - For 90 modules of length, this translates to an overall bar code width of **17.1 mm**



Printing orientation

- We also noticed that there were some linear gaps in our bar codes
- Asked bar code printer manufacturer to run some tests for us
- Bar code printer manufacturer confirmed that some of our bar codes were printing with the bars parallel to the direction that the armband is printed
- Printer maintenance is an issue
- Thermal elements and printer pins can misfire...



A



B



Scanner issues

- Rare substitution errors resulted in numbers of different character lengths
- Scanner read the bar code as a different symbology (code 39)
- Scanner manufacturer stated that we could not restrict this particular scanner to only read Code 128
- The scanner also did not have the capability to read 2D bar codes



Not all scanners are equal...

Table 2. Defective bar code substitution and rejection rates.^a

Bar code	Roche ACCU-CHEK		Metrologic MS 9540		Symbol LS-9100-411 BA		ZBA AS-8210		Adesso NUSCAN 1000U	
	Substitution rate, % (95% CI)	Rejection rate, % (95% CI)	Substitution rate, % (95% CI)	Rejection rate, % (95% CI)	Substitution rate, % (95% CI)	Rejection rate, % (95% CI)	Substitution rate, % (95% CI)	Rejection rate, % (95% CI)	Substitution rate, % (95% CI)	Rejection rate, % (95% CI)
1	75.6 (61.2–85.9)	0	0	0	56.5 (41.2–69.1)	0	48.9 (35.0–63.0)	0	51.1 (37.0–65.0)	0
2	28.9 (17.6–43.5)	0	0	33.3 (21.3–48.0)	0	86.7 (73.4–94.1)	0	0	0	66.7 (52.0–78.7)
3	17.8 (9.0–31.6)	0	0	33.3 (21.3–48.0)	0	100	0	0	2.2 (0–12.6)	0
4	11.1 (4.3–24.0)	0	0	0	0	33.3 (21.3–48.0)	2.2 (0–12.6)	0	2.2 (0–12.6)	0
5	13.3 (5.9–26.6)	66.7 (52.0–78.7)	0	66.7 (52.0–78.7)	0	100	0	66.7 (52.0–78.7)	0	66.7 (52.0–78.7)
6	11.1 (4.3–24.0)	88.9 (76.0–95.6)	0	100	0	100	2.2 (0–12.6)	97.8 (87.4–100)	2.2 (0–12.6)	97.8 (87.4–100)
7	24.4 (14.1–38.8)	2.2 (0–12.6)	0	2.2 (0–12.6)	17.8 (9.0–31.6)	0	0	6.7 (1.6–18.5)	0	0
8	80.0 (66.0–89.5)	15.6 (7.4–29.1)	0	100	17.8 (9.0–31.6)	66.7 (52.0–78.7)	2.2 (0–12.6)	95.6 (84.4–99.6)	4.4 (0–9.9)	91.1 (78.7–97.0)
9	40.0 (27.0–54.6)	0	0	0	60.0 (45.4–73.0)	0	28.9 (17.6–43.5)	0	53.3 (39.0–67.1)	0
10	73.3 (58.8–84.2)	2.2 (0–12.6)	0	88.9 (76.0–95.6)	77.8 (63.5–87.6)	0	2.2 (0–12.6)	8.9 (3.0–21.3)	4.4 (0.4–15.6)	48.9 (35.0–63.0)

^a Substitution rates [(number of incorrect scans/total number of attempted scans) × 100] and rejection rates [(number of failed scans/total number of attempted scans) × 100] are presented for the 10 defective bar codes by using 5 different bar code scanner models.

Snyder ML, Carter A, Jenkins K, Fantz CR. Patient misidentifications caused by errors in standard bar code technology. *Clin Chem*. 2010;56(10):1554-1560.



Error rates

- Theoretical error rate of Code 128
 - 1 substitution error in every 2.7 million to 37 million scans
 - Assumes **pristine** conditions for scanner, printer and no damage
- Actual error rate
 - At our institution, more like 1 substitution error in at least every 88,000 scans
- Big difference



Linear (1D) Bar Code challenges

- Disadvantages
 - Very space intensive (take up a lot of real estate) for the amount of data encoded
 - Can usually only encode one identifier because of space
 - No way to know what piece of data was encoded into the bar code
 - Is it an MRN, Financial number or Master Patient Index?
 - People don't realize that implementation requires attention to many details

Snyder ML, Carter A, Jenkins K, Fantz CR. Patient misidentifications caused by errors in standard bar code technology. *Clin Chem*. 2010;56(10):1554-1560.



2D Bar Codes

- Encoded data represented in two dimensions
- Two major types
 - Stacked 1D
 - e.g., PDF417
 - Matrix (QR code, DataMatrix, Aztec)
- “Pathology Informatics Summit 2018”
- X-dimension = 2 pixels

DataMatrix



QR code (L)








PDF417



For comparison, Code 128:



2D Matrix Bar Code Comparison

Symbology	Quiet Zone	Min Size (modules)	Max size (modules)	Max alpha-numeric characters	Error Correction Options	Orientation-independent	Capable of Reflectance-reversal	Extended Channel Interpretation	Structured append max # symbols	Recommended version
Data Matrix 	Minimum 1X Rec. 2X or 4X, all 4 sides	10 x 10	144 x 144	2,335	ECC 200 has only one option (Reed-Solomon)	Yes	Yes	Yes	16	ECC 200
Data Matrix 	Minimum 1X Rec. 2X or 4X, all 4 sides	8 x 18	16 x 48	72	ECC 200 has only one option (Reed-Solomon)	Yes	Yes	Yes	16	ECC 200
Aztec 	NONE NEEDED	15 x 15	151 x 151	3,067	From 5% to 95%, ≥ 23% recommended	Yes	Yes	Yes	26	Original version
QR Code 	Minimum 4X required, all 4 sides	21 x 21	177 x 177	4,296	L (%) M (15%) Q (25%) H (30%)	Yes	Yes	Yes	16	QR Code Model 2
Micro QR code 	Minimum 2X required, all 4 sides	11 x 11	17 x 17	21	L (%) M (15%) Q (25%)	Yes	Yes	Yes	NONE	QR Code Model 2







2D Bar Codes

- Data integrity checks are MUCH more robust
 - e.g., DataMatrix performs integrity checks in the X-dimension, Y-dimension and diagonally
- Error correction algorithms can be used
 - Redundant encoding of data
 - Will slightly lessen the data that can be encoded
 - Uses algorithms to determine which components of the bar code are undamaged and can be read
 - Several bar codes allow for up to 30% damage to the bar code and still generate an accurate scan



Error Correction

Bar Code Content	Level of Error Correction	Bar Code <i>(X-dimension = 2 pixels)</i>
Pathology Informatics Summit 2018	L	
Pathology Informatics Summit 2018	M	
Pathology Informatics Summit 2018	Q	
Pathology Informatics Summit 2018	H	



2D Bar Codes

- Because the data density is higher, no excuses for encoding only one identifier
- We don't use a single identifier for anything else in medicine...it's not OK for bar codes either.



Bar Codes

Type of Error	Estimated Unrecognized Character Error Rate
Manual Entry	1 in 300
1D bar code	1 in 88,000* to 37 million
2D/matrix bar code	1 in sextillions (10^{21})

Snyder ML, Carter A, Jenkins K, Fantz CR. Patient misidentifications caused by errors in standard bar code technology. *Clin Chem*. 2010;56(10):1554-1560.



Linear (1D) vs. 2D Bar Codes

	1D Bar Code	2D Bar Code
Data density – amount of data it can contain	Usually only 1 identifier	Multiple identifiers
Can encode redundancy of data	No	Yes
Damage/Printer Error Correction and Detection Algorithms	No	Yes
Number of data integrity checks	0 (most 1D bar codes) OR 1 (Code 128 only)	>1
Ease of installation	Easy	Harder
Easily read from curved surface (specimen tube)	Yes (if oriented properly)	No

2D Bar Codes and Curved Surfaces

- Military grade 2D symbols require:
 - Minimum X-dimension of 10 mil (0.254 mm)
 - Overall size of symbol should be < 16% of diameter of curved surface
 - Smallest standard (not bullet) peripheral blood tube is 12 mm
 - Maximum size of symbol would be 1.92 mm
 - 75.59 mil
 - 7 modules across
- Military grade assumes low resolution (standard) camera
 - Testing underway
 - High resolution readers will allow for a higher % diameter
 - Higher resolution readers currently have similar cost to low resolution readers



More to the story...

- Upgrade to our LIS in 2013
- Accession numbers

– 11 characters



14 characters



- We were already close to the limit of our white space on the bar code label
- Improperly printed bar codes had no quiet zone
- Had to truncate one digit (the tens digit of the year) to make it fit (accession numbers not unique every 10 years)
- More reason for new CLSI standard



Bar Code Standards

Asset	Current Bar Code Standard	Required Bar Code symbology	Comments/Reference
Clinical Laboratory Labels	CLSI AUTO02-A2	Code 128 A Code 128 B Code 128 C	<ul style="list-style-type: none">• Code 128 has required check digit• All other linear bar codes have NO check digit• Bar Code content <u>not</u> specified• Code 39 (<i>optional</i> check digit) <i>deprecated years ago...</i>• CLSI AUTO12-A regards human-readable component only• Standard for 2D bar codes (AUTO14) is in progress
Blood products (medical products of human origin)	ISBT 128	Code 128 or 2D	<ul style="list-style-type: none">• Specifications for symbology, encoded content, printers, and scanning software (increases safety)• accepted by FDA for medical products of human origin (many reference here and here)• AABB requires all blood labeled on or after May 1, 2008 to be labeled with ISBT128 (Codabar no longer allowed)

Bar Code Standards

Asset	Current Bar Code standard	Required Bar Code symbology	Comments/Reference
Anatomic Pathology Specimens	No standard available for bar code	None	<ul style="list-style-type: none">• CAP Uniform Labeling of Blocks and Slides standard applies to human-readable component only• Standard for 2D bar codes (AUTO14) is in progress
Medications	GS1-128 (UCC/EAN-128) or HIBCC	Code 128	<ul style="list-style-type: none">• Bar Code symbology must be linear• Must contain National Drug Code at a minimum• Syntax should be compliant with HIBCC or UCC/EAN
Patient armbands	None	None	<ul style="list-style-type: none">• Critical bar code• No standards

Déjà vu

- Two months after my arrival at CHOA in 2015, substitution errors were reported which are caught by middleware before getting to the patient
- DIFFERENT point of care device (different manufacturer)



Troubleshooting process

- **Priority #1: Get the original scanned bar code(s)!**
 - They are not always on the patient. ☹️
- Look for signs of damage and printer misfires
 - Are the printers getting frequent maintenance?
 - Are the bar code bars being printed parallel to the direction of the printer feed?
- Determine the X-dimensions of:
 - Printed bar code
 - Minimum X-dimension that bar code scanner can read
 - Are they compatible?



Proactive Checklist for Linear Bar Codes

- Determine the X-dimension of the printed armband bar code
- Is this X-dimension compatible with all scanners that are reading the bar code?
- Are printers that print bar codes (especially armbands) undergoing routine and frequent maintenance?
 - Examine example printed armbands for printer misfires
- Migrate to 2D if possible (all other stuff still applies)
- Educate your end-users!



Bar Code Quality 101

To ensure a fast and accurate scan...

Do **NOT** scan bar codes
that look like this



Problems:

- Black bars have white specs
- White spaces between bars have black smudges

Poor Quality Bar Codes

Scan bar codes that look
like this:



If your patient doesn't have clean and sharp bar codes like this one:

1. Reprint the bar coded item (armband or label)
2. If the bar code still doesn't look sharp, call _____

Future Work

- CLSI AUTO14 Standard in Progress
 - Use of Two-dimensional Barcoding in Clinical and Anatomic Pathology Laboratories
 - Patient armbands are not in scope
- We need better standards for automated patient identification
 - Data encoded into patient armbands



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Questions?