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Original Article

Donor Screening Analyzers ASTM Protocol adaptation for Systems Communication

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Abstract *- Donor screening is a critical component in ensuring the safety and efficacy of blood transfusions. Modern clinical laboratories employ automated donor screening analyzers to streamline and enhance the accuracy of this process. To maintain data integrity and interoperability, these systems rely on standardized communication protocols. This paper explores the adaptation of ASTM (American Society for Testing and Materials) protocols for system-to-system communication between donor screening analyzers and laboratory information systems (LIS). It highlights the importance of bidirectional and upload-only communication modes, details the configuration steps required to initiate communication, and explains the role of ASTM standards such as E1394-91 and E1381-91 in establishing reliable data transmission pathways. The architecture of communication frames, messages, and sessions is discussed in depth to illustrate the data flow and control mechanisms. Additionally, this paper outlines the typical analyzer workflow, emphasizing the need for seamless integration to minimize manual entry errors and improve laboratory efficiency.*

Keywords *- Donor Screening, Blood Analyzers, ASTM Protocol, Laboratory Information Systems (LIS), Clinical Instrument Communication, E1394-91, E1381-91, System Integration.*

1. Introduction

Donor screening is the process of certifying blood products for Transfusion. It is the process to ensure the donated blood is safe and free from infectious diseases. The AABB (Association for the Advancement of Blood & Biotherapies) has defined standards for blood certification, and it is conducted in accordance with federal and state regulations to protect Donor safety, and to ensure the blood collection is done safely right from recruitment, screening, donation, and testing. The safety, purity and potency of the blood collection is critical for ensuring the health and safety of the blood donor before, during and after collection, including the use of minimum hemoglobin requirements and safety considerations for nonbinary donors, information on blood donation and iron health and limiting donation frequency.

The donor screening process also protects the safety of the transfusion recipient by identifying eligible donors who meet specific criteria to help ensure blood safety.For the blood to travel safely from donor to patient, great care must be taken at each step in the process from the collection of blood to the transfusion of the patient. And today's financially strained environment calls for enhanced cost-efficient automation of that process to deliver a reduced labor-intensive solution within a process-controlled environment. There are various Donor Screening Analyzers in the market with varying capabilities.

The interfaces between the laboratory computer and the donor screening analyzer the below steps are mandatory.

- The hardware connections required for appropriate transfer
- The modes of communication used by the systems
- The data transmission protocol from one device to another.

The typical steps followed by the Laboratory Technician on the Donor Screening Analyzer:

1. The Lab personal enters all Assay information, Kit lot info data entered on the OAS Server.
2. Sample, plates, specimen diluent, and controls loaded at Analyzer Pipetter.
3. All loaded information logged/checked by the OAS Server
4. If all info agrees, Analyzer will begin pipetting
5. Finished pipetted plate is transferred to the Summit Processor
6. Summit Processor will check with the Assay Syster Server to make sure the plate is ready to process
7. Summit Processor will complete the 5 mandated tests steps, prompt for reagent loading, and read the plate

8. Results from the Summit Process are sent back to the Assay Server, which performs calculations from Summit Processor results to determine plate validity and sample status.
9. Assay Server (or Workstation) communicate results to the Laboratory Information Systems.

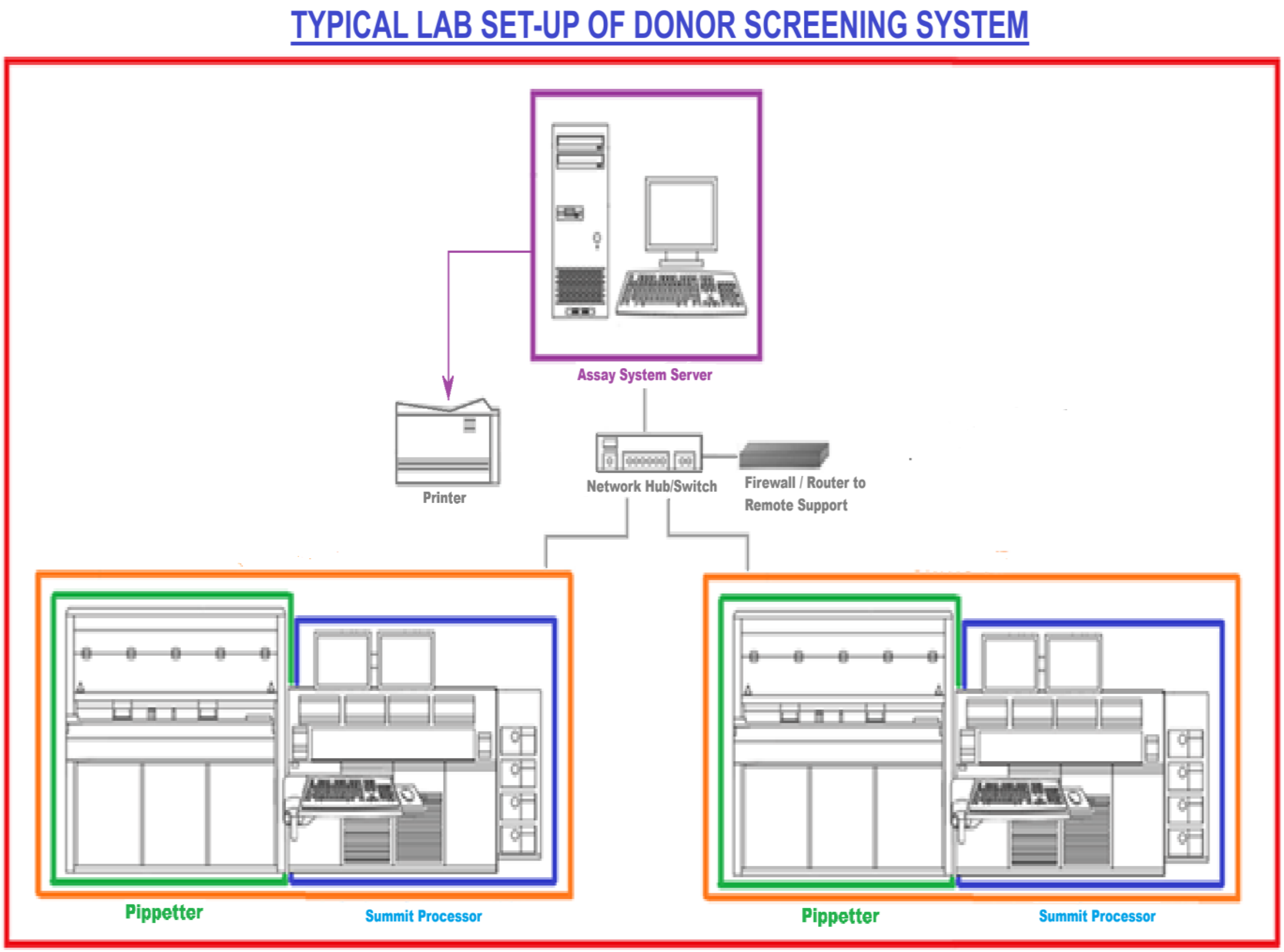

Fig 1: Lab set-up of donor screening system

1.1 Delving Deeper into ASTM Communication Protocol:

To create the optimum processing environment for a given laboratory. When you install an Analyzer, you must configure it to enable communications. Before connecting systems, you must have detailed knowledge of the interface capabilities of the laboratory computer and the systems. The Analyzers have No communication as the default setting, we need to enable Communication, Configure Ports which will change to start communication. The upload-only option allows the analyzer to send patient test results to the laboratory computer. It also permits the upload of patient and doctor demographic data. The upload-only mode requires that the laboratory operator enter all test order requests either manually or automatically from the laboratory computer depending on the capability of the analyzer.

This manual entry increases the possibility of errors and additional staff time. The upload mode protects data integrity and provides acknowledgment of receipt of data and checksum validation from the laboratory computer. The bidirectional mode is available on many modern analyzer systems and allows the laboratory computer to download test orders to the systems. It then allows the systems to send test results back to the laboratory computer. We have analyzers that integrate with (LIS) Laboratory Information Systems. It is a robust system with significant flow control, handshaking, and data acknowledgment features that protect data integrity. The ASTM communications protocol was created by the American Society for Testing and Materials (ASTM). It is designed specifically for medical devices and supports the transfer of an array of medical data.

It enables speedy communication while using several data protection mechanisms like acknowledgments, timing mechanism, and data recovery procedures. It also establishes a national standard for communication among medical facilities. The ASTM protocol ensures data integrity while handling a large volume of data. Information about this protocol can be found in a publication produced by ASTM: Annual Book of ASTM Standards. Designation: E 1394-91: “Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems” and Designation: 1381-91: “Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems.” ASTM uses several terms to indicate the logical building blocks of the data transmission. These are called frames, messages, and sessions.

- **Frames:** The basic unit of communication for the data link layer. Based on the size of the message, there can be more than one frame. Frames are sometimes referred to as packets.
- **Messages:** The actual records containing the data on patients, sample programs and test orders, test results, comments, and other data. Messages contain one or more frames. A message contains one record at one given level in the record hierarchy.
- **Sessions:** The communication events. They contain all the control characters and messages sent, starting from the establishment phase and ending with the termination phase.

ASTM also refers to “test orders” and “test batteries” rather than “sample programs.” For consistency, the request for a series of tests on a patient sample will be referred to as a sample program in this manual. For the Donor Screening “assay” is often used rather than “test.” In communicating from one station to another, ASTM, like other protocols, designates certain ASCII control characters as restricted characters that cannot appear in message text.

Table 1: ASCII Meaning and Decimal Value

ASCII	Meaning	Decimal Value
ACK	Positive Acknowledgment	6
DC1	Control Q	17
DC2	Control R	18
DC3	Control S	19
DC4	Control T	20
ENQ	Inquire or Enquire	05
EOT	End of Transmission	04
ETB	End of Text Block	23
ETX	End of Text	03
LF	Line Feed	10
NAK	Negative Acknowledgment	21
SOH	Start of Header	01
STX	Start of Transmission	02
DLE	Data Link Escape	16
SYN	Sync	22

1.2 Types of Frames

The maximum character limit for a frame in ASTM is **247 characters** (including overhead). If a given message is less than 240 characters, it is sent in an end frame with an <ETX>, checksum, <CR>, and <LF>. If, on the other hand, a message is greater than 240 characters, the message is sent in intermediate frames containing this structure <ETB>, checksum <CR>, <LF> with the final part of the message in an end frame. In other words, an <ETB> indicates that the message contains more than one frame. The below table summarizes the layout for intermediate and end frames. Note that every message contains a frame number as well as two checksum characters for error checking to ensure data integrity.

1.3 Frame Numbering (FN)

The frame number must immediately follow the <STX> character. It identifies the frame so that, in the event of a retransmission, the receiving device can distinguish it from a new frame. The FN begins with 1 and continues until 7. If more than seven frames are sent in one session, the counter rolls over to 0 and continues in the same manner.

Table 2: Frame Structure and An Intermediate Frame An End Frame

Frame Structure	
An Intermediate Frame	
<STX> FN text <ETB> C1 C2 <CR> <LF>	
An End Frame	
<STX> FN text <ETX> C1 C2 <CR> <LF>	
C1	Most significant ASCII character of checksum 0-9 and A-F
C2	Least significant ASCII character of checksum 0-9 and A-F
ETB	End of Text Block
ETX	End of Text
FN	Single digit from 0-7 for Frame Number
CR	Carriage Return
LF	Line Feed
STX	Start of Transmission
text	Data Content of Message

2. Session Establishment

A session consists of the transfer of one or more frames from one station to another. It is a unit of communication between two stations or devices. A session begins with the Establishment Phase and ends with the Termination Phase and includes all the events occurring within the session. Either station can initiate a session when it has records to send: the analyzer, for example, may wish to send results (an upload session) or the laboratory computer may wish to send a sample program (a download session). The sender first attempts to determine if the link is in a neutral state, that is, free for use. It notifies the receiver that it is ready to send records by transmitting the <ENQ> control character. The receiver may reply in one of two ways. If it is ready to receive records, it sends a positive acknowledgment, <ACK>, and this completes the Establishment Phase. But if the receiver is not ready to receive, it transmits a <NAK>, indicating it is not ready.

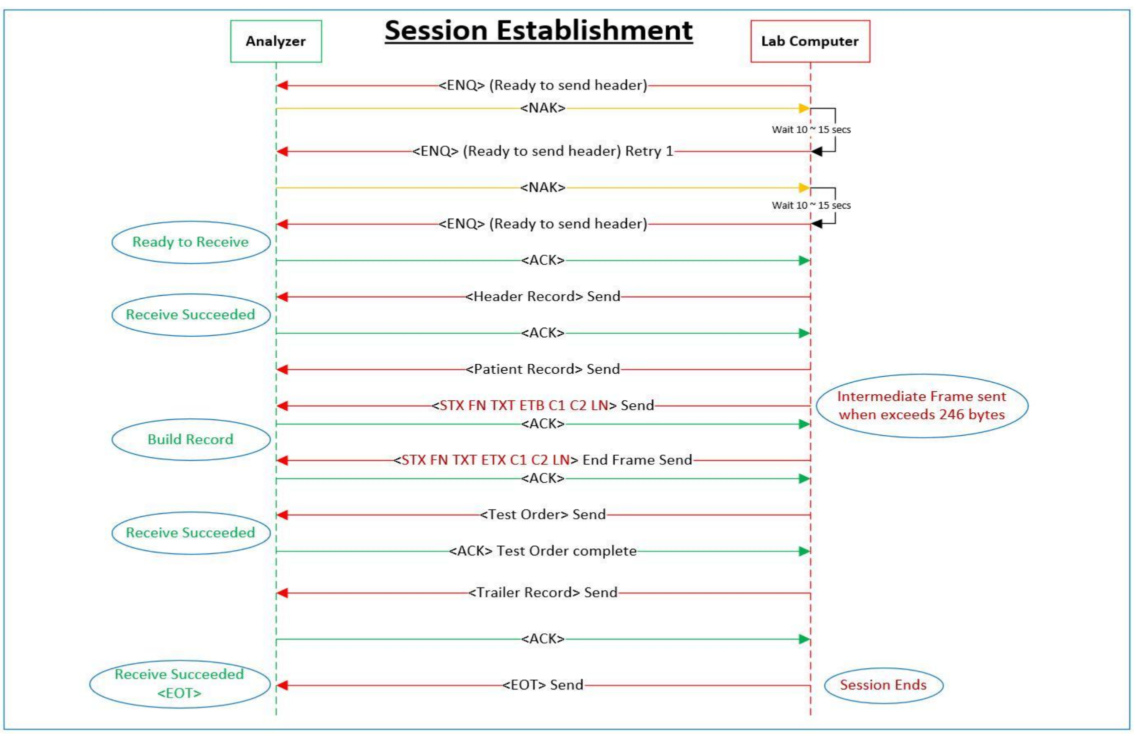

Fig 2: Session Establishment

If the sender transmits an enquire <ENQ>, it requires a reply within 15 seconds. If it receives no reply after 15 seconds, the sender considers the link to be in a neutral state. When a sender receives a <NAK>, it must wait at least 10 seconds before it tries again. In attempting to establish a session, ASTM does not specify a particular limit for number of repeated attempts. After a device establishes a session, it begins its transmission of message frames with supporting control information. ASTM provides several timers and monitoring mechanisms to ensure speed, accuracy, and completeness throughout the transfer phase. These are described in the listing.

2.1 Receiver Timers in Transfer Phase

The receiver sets a timer of 30 seconds in which to receive either a frame or an <EOT>. If either of these is not received in the time limit specified, the receiver discards the frames that were received since the last successful save point and considers the line in a neutral state.

2.2 Acknowledgments

The ASTM protocol requires that the sender stop after each frame is sent and await an acknowledgment. The acknowledgment must occur frame by frame. Before responding, the receiver must monitor its own continuing capacity and check for error conditions. Specifically, the receiver checks the following items:

1. The frame number
2. The checksum value
3. The receipt of an <ETB> or <ETX>

The receiver then responds with one of these three acknowledgments:
<ACK> The last frame was successfully received. Send next frame.
<NAK> The last frame was not successfully received. Retransmit last frame.
<EOT> The last frame was successfully received. Please stop transmission. When the receiving station of the current session sends an <EOT> as an acknowledgment, it is urgently requesting the sending device to stop sending and put the line in a neutral state, allowing the receiver to establish its own session.

2.3 Timers for Acknowledgments

The sender waits for an acknowledgment of receipt. If this does not occur within 15 seconds, the sender cancels the message and terminates.

2.4 Interrupt Timers

A receiver can request an interrupt by sending an <EOT>. The sender is not required to honor the request but may do so. If the sender stops transmission and the receiver does not enter the establishment phase in 15 seconds, the sender may re-enter the establishment phase.

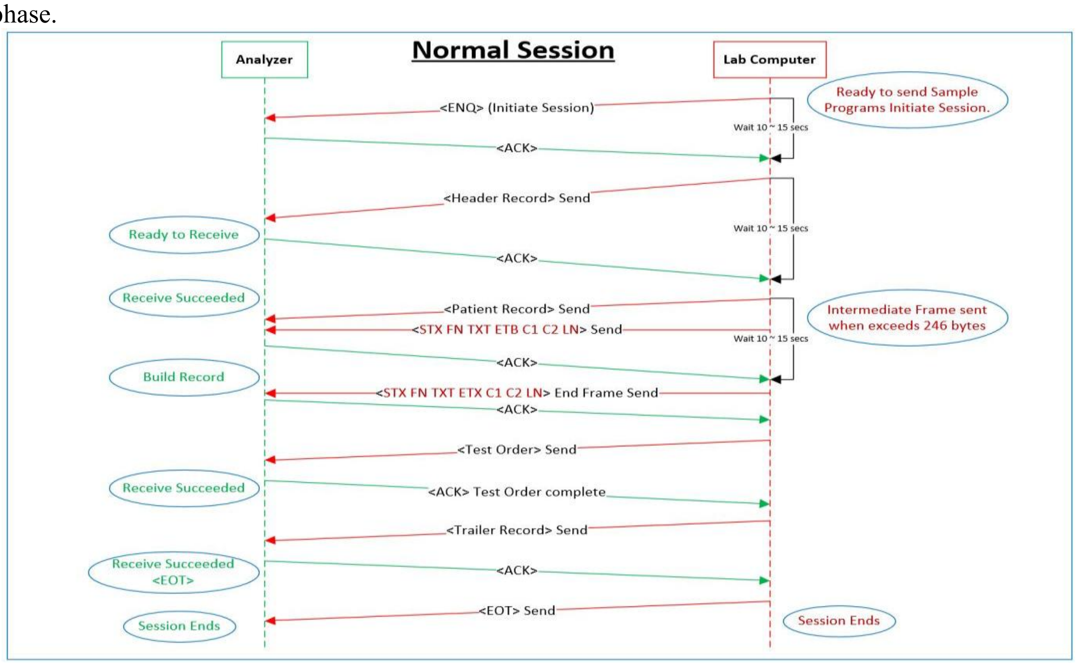

Fig 3: Normal Session

3. Session Contention

When either the laboratory computer or the analyzer initiates a session, the session flows in one direction at a time. However, when the laboratory computer and the analyzer both wish to initiate a session at the same time, that is, when they send simultaneous <ENQ>s, they are in contention. According to the ASTM protocol, when in contention, the laboratory computer must give way to the analyzer. When contention occurs, two session contention timers apply, one for the analyzer and one for the laboratory computer. When the analyzer receives an <ENQ> in reply to its own <ENQ>, indicating a state of contention, it must wait one (1) second before retransmitting an <ENQ> to establish a session. The laboratory computer, when in a state of contention, must wait 20 seconds for an <ENQ> from the analyzer. If it does not receive an <ENQ> in that time frame, the line is in a neutral state and the laboratory computer can then try to establish a session itself by sending an <ENQ> again.

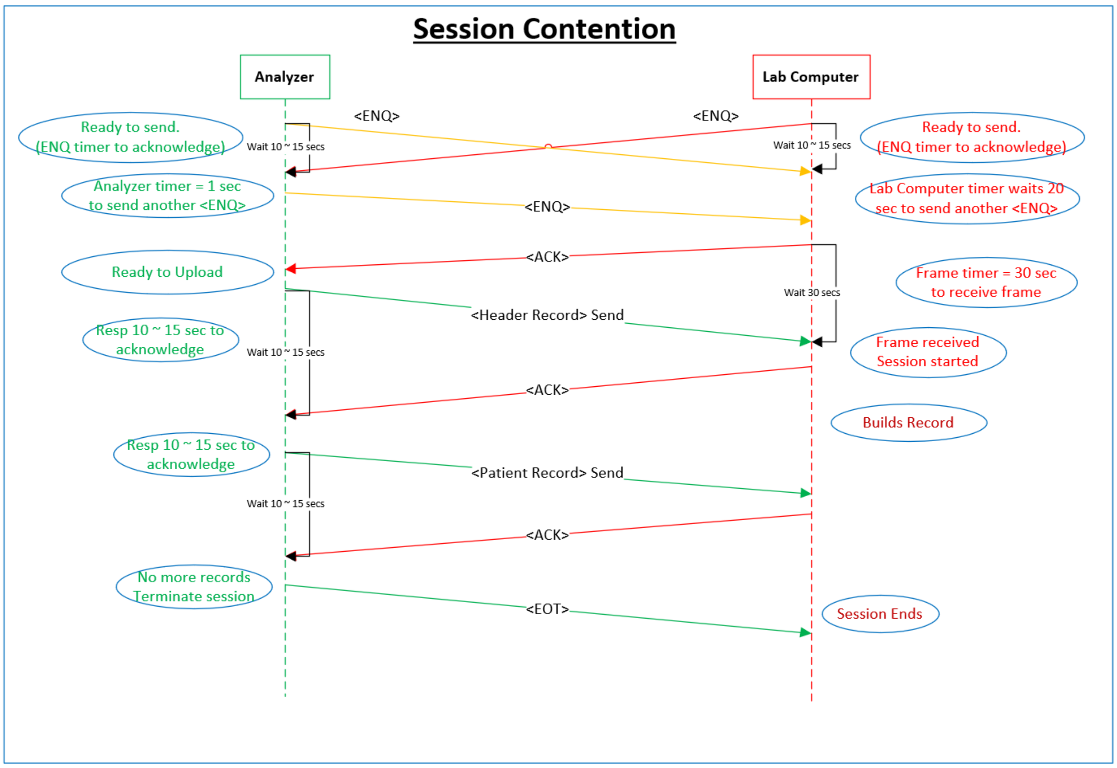

Fig 4: Session Contention

4. Session Duration

Sessions can extend for an unspecified amount of time. However, it is helpful to recognize that if there is an analyzer backlog in reporting results, an upload session may be quite lengthy.

4.1 Transmission Errors and Condition Codes

If the Donor Screening System detects an error during an upload session or a download session, it reports the error to the master computer software as a condition code for the operator. At the link level, if the Donor Screening System is uploading, it tries to resend the <NAK>ed frame six times; then it cancels and returns the line to a neutral state. When this happens, the Donor Screening System remembers the frame sent in error and retransmits it later. If the Donor Screening System is receiving a frame with an error, it <NAK>s the frame. It repeats this up to six times and then, if the frame is still in error, it cancels the session, returning the line to a neutral state.

4.2 Broadcasting Samples

If a laboratory has more than one analyzer, it can choose to implement an analyzer-supported broadcast feature. In broadcasting, the laboratory computer sends a given sample program to all analyzers simultaneously. Once the patient sample corresponding to the sample program has been loaded onto a particular analyzer, that analyzer can then actually process the order. The broadcasted sample program will remain on the other analyzers until deleted. On the Donor Screening system, to delete a sample program manually, the operator must resubmit the sample program with the same specimen ID and universal test ID, but with the universal test ID empty or the action code equal to ‘C’ for cancel. The Donor Screening system recognizes this string combination as a request to cancel. Like other analyzers, the Donor Screening system ignores any broadcasted sample programs with analytes that do not pertain to it. Since it has unique values for body fluid, it also ignores any sample programs with unrecognized specimen types.

4.3 Summary of Key Features

- ASTM is a simplex stop and wait protocol.
- Its default configuration is 9600 baud, 8 bits, with no or odd parity checking and 1 stop bit.
- All transmission is in ASCII with these restricted characters: ACK, DC1, DC2, DC3, DC4, DLE, ENQ, EOT, ETB, ETX, LF, AK, SOH, STX, SYN.
- ASTM transmits data records encapsulated in frames that must be acknowledged frame by frame.
- Error conditions result in <NAK> responses that require a retransmission.
- Timers exist for acknowledgments, frame reception, and replies.
- Receiver interrupts are allowed any time the receiver.

5. Conclusion

The integration of ASTM communication protocols into donor screening analyzers represents a significant advancement in the automation and reliability of blood screening workflows. By enabling standardized, secure, and efficient data exchange between analyzers and laboratory information systems, laboratories can ensure higher accuracy, reduce manual entry errors, and enhance overall operational efficiency. The bidirectional communication model, supported by ASTM protocols E1394-91 and E1381-91, plays a crucial role in facilitating real-time data transfer, validation, and system synchronization critical for managing the safety and traceability of donor information and test results. As donor screening becomes increasingly complex and regulated, adopting such robust communication frameworks is essential for ensuring compliance, improving turnaround times, and maintaining the highest standards of donor and patient safety. The future of donor screening lies in seamless interoperability, and ASTM protocol adoption is a vital step toward that goal.

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