

Global Service Standards

How to use Generic Codes for Application Issues

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DOCUMENT INFORMATION

General Information

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Document History

Version	Reason for change	Date (mm/dd/yyyy)
1.0	first release	02/06/2003
1.1	added 7 problem category/cause code combinations	07/05/2004
2.0	added Please Specify codes and Not Applicable codes	01/27/2005
4.0	changed to v4.0 to be compliant with DocIT versioning added section Problem Description Visits changed expanded definitions of codes P00, P14, P99, C00, C12, C99, X00, X13 & X99	04/03/2006

5.0	<p>Introduction chapters shortened</p> <p>Changed definitions for codes P07, P10, P14, C02, C12, C16, C17, C23 and X02</p> <p>Changed expanded definitions for codes P99, C99 and X99: setting of these codes also depends on IT product codes</p>	03/20/2007
6.0	<p>New rules for mandatory problem description reporting</p> <p>Added Category codes P97, P98, renamed code P14</p> <p>Added Cause codes C97, C98, renamed code C12</p> <p>Added Fix codes X97, X98</p> <p>Removed dependencies between Category & Cause codes (all relating to Not Applicable codes)</p>	01/15/2008
7.0	<p>Changed explanation for code P04, P05</p> <p>Removed code X13</p> <p>Added Category/Cause combination P05/C18</p>	As of approval

Distribution

Department / Area / Function
via DMT homepage

Purpose

The purpose of this document is to provide additional information for local service organizations on how to use Global Service Standard codes when reporting application problems fixed by service specialists.

Provision of this additional “How to use –“ information is needed to ensure that all country organizations use Global Service Standards in their local CRM tools in such a way as to provide comparable reporting output, to enable us to utilize this information to improve our products.

Mandatory Problem Description Reporting

If the First Classification Code (which documents the customer allegation) classifies the respective case as complaint it is mandatory to provide a coded problem description. This can be done either with

- Hardware codes,
- IT / Software codes or
- Application codes (which are described in this document)

Complaint-type First Classification codes are

- Assay Performance,
- Instrument Malfunction,
- Software Malfunction,
- Labeling / Documentation / Packaging or
- DC-Assessment

and a proper problem description reporting is a must for these cases.

In all other cases it is ok to leave the problem description codes as “Please Specify”. This especially applies to “Roche initiated activities” (like PM or installations), for “Information Requests” additional information might be helpful therefore it is recommended to also use these codes for this type of cases.

Problem Category Codes

Code	Description	Definition
P00	Please Specify	Default selection in Clarify
P01	Assay Performance – Imprecision	Deviation from an expected coefficient of variation (CV) for a assay result
P04	Assay Performance – Inaccuracy	Deviation of an expected value for a assay result
P05	Assay Performance – Other	Assay performance issues not related to assay imprecision or inaccuracy e.g. linearity, no result, staining issues etc.
P06	Information Customer Request	Request from the customer for information on non-performance related issues
P07	Labelling / Documentation	Issues related to labelling / documentation of applications related products e.g. bar codes package inserts etc
P08	Packaging	Issues related to the packaging of products supplied by Roche
P10	Shipping / Delivery	Issues related to product logistical topics, e.g. product availability
P14	No problem found	No problems found
P97	Empty Field	for internal data processing, not to be used in Clarify
P98	Not Global	for internal data processing, not to be used in Clarify
P99	Not Applicable	for internal data processing, not to be used in Clarify

Cause Codes

Code	Description	Definition
C00	Please Specify	Default selection in Clarify
C01	Customer Technique / Handling	Issues related to customer or laboratory personal proficiency
C02	Product Does Not Meet Customer Expectations	Product is within Roche published specification, but the customer expectation is not met
C03	Non-Roche Product	Failure of or caused by a non-Roche product used in combination with a Roche supplied product
C04	Patient Sample	Issues or problems related to measurements and or handling of patient samples
C05	External Control / Survey Sample	Issues related to measurements / handling / storage of external controls or survey control samples
C06	Outdated Assay Calibration	Issues related to an inaccurate or invalid calibration curve
C07	Method Comparison	Request for assistance with method comparisons
C08	Product Configuration Issue	Problems related to product design or manufacture
C09	Shipment Error	Problems relating to the product integrity due to shipping errors
C10	Storage	Problems relating to product integrity due to storage on customer site
C11	Wrong Software / Assay Protocol	Issues related to incompatibility of assay protocols or software
C12	No cause found	No cause found, e.g. problem could not be reproduced or verified
C13	Code Identification Missing / Unreadable / Incorrect	Issues related to the inability of analytical systems to recognize machine readable codes
C14	Label Missing / Unreadable / Incorrect	Issues related to readability / availability / accuracy of product labelling

Code	Description	Definition
C15	Package Insert / Roche Documentation	Issues concerning Roche supplied product documentation and or package inserts
C16	Backorder / Product Availability	Issues regarding non-availability or back-order delivery of Roche supplied products
C17	Late / Wrong Delivery	Issues regarding timing or incorrect delivery of Roche supplied products
C18	Component Missing / Wrong / Damaged	Problems related to package contents of Roche supplied products
C20	Package Integrity	Issues related to internal or external packaging of Roche supplied products
C23	Product Introduction / New Product / Version Change	Issues related to new product introduction or version changes
C24	Environmental	Issues related to the laboratory environment effecting assay results e.g. room temperature, water quality etc
C97	Empty Field	for internal data processing, not to be used in Clarify
C98	Not Global	for internal data processing, not to be used in Clarify
C99	Not Applicable	for internal data processing, not to be used in Clarify

Fix Codes

Code	Description	Definition
X00	Please Specify	Default selection in Clarify
X01	Application Loaded / Updated	Customer or Roche representative update of specific application parameters
X02	Product Bulletin / Customer Letter	Forward published / formal information to customer in response to their call
X03	Customer Training / Education	Training to resolve a specific customer issue, either on site, by telephone or by remote diagnostics
X04	Maintenance / Cleaning / Lubricating	Resolving the customer problem by giving guidance / advice on maintenance, cleaning or lubricating
X05	No Fix	Unable to resolve problem or issue, or unable to replicate problem
X06	Product Replacement	Send replacement product e.g. Reagent, consumable, spare part/CC
X07	Provide Documentation	Provide product specific documentation e.g. package insert, bar code etc
X08	Provide Information	Provide informal advice or information on customer request
X09	Provide Materials	Provide materials, Roche or non-Roche for evaluation / Trial / Customer use
X10	Recalibrate / Readjust	Resolving the customer problem by giving guidance / advice through recalibration or readjustment procedures

Code	Description	Definition
X11	Repair	Dispatch to Field Engineering
X12	Repeat / Re-run	Advise or guide customer through repeat / rerun procedure
X97	Empty Field	for internal data processing, not to be used in Clarify
X98	Not Global	for internal data processing, not to be used in Clarify
X99	Not Applicable	for internal data processing, not to be used in Clarify

Problem Category & Cause Code Matrix		Please Specify	Assay Performance imprecision	Assay Performance Inaccuracy	Assay Performance Other	Information Request	Labelling / Documentation	Packaging	Shipping / Delivery	No problem found
		P00	P01	P04	P05	P06	P07	P08	P10	P14
C00	Please Specify	X	X	X	X	X	X	X	X	X
C01	Customer Technique/ Handling		X	X	X	X				X
C02	Product does not meet customer expectations		X	X	X	X	X	X		X
C03	Non-Roche product		X	X	X	X	X			X
C04	Patient sample		X	X	X	X				X
C05	External Control / survey sample		X	X	X	X				X
C06	Outdated assay calibration			X	X					X
C07	Method comparison			X	X	X				X
C08	Product configuration issue				X			X		
C09	Shipment error		X	X	X				X	X
C10	Storage		X	X	X	X				X
C11	Wrong software / assay protocol		X	X	X	X				X
C12	No cause found		X	X	X	X	X	X	X	
C13	Code identification missing / unreadable / incorrect						X			
C14	Label missing / unreadable / incorrect						X			
C15	Package insert / Roche documentation						X			
C16	Backorder / Product availability								X	
C17	Late / wrong delivery								X	
C18	Component missing / wrong /damaged				X			X		
C20	Package integrity							X		
C23	Product introduction / new product / version change		X	X	X	X	X	X	X	X
C24	Environmental		X	X	X	X				

Problem Code Expanded Definition

P00	Please Specify	Default selection in Clarify
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Code P00 Please Specify. This code must not be used in a problem description visits (see above list of activities)! It is only available as a default code prior to selecting the actual problem category code.

P01	Assay Performance – Imprecision	Deviation from an expected coefficient of variation (CV) for a assay result
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Code P01 Assay Performance – Imprecision, is to be used when defining problems associated with imprecise results. Typically this would be when a number of control or pool sera are assayed and the resulting spread of results are greater than expected.

P04	Assay Performance – Inaccuracy	Deviation of an expected value for a assay result
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Code P04 Assay Performance – Inaccuracy, is to be used when defining problems associated with inaccurate patient or control results. Typically this would be when control sera or patient samples are reported outside their expected value or range.

P05	Assay Performance – Other	Assay performance issues not related to assay imprecision or inaccuracy e.g. linearity, no result, staining issues etc.
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Code P05 Assay Performance – Other, is to be used when defining non-accuracy or imprecision related problems. Typically this would be where problems are encountered associated with assay linearity, carry-over, no result, or non-specific assay problems, such as assay calibration issues. This code is also to be used for staining issues with Histology products, e.g. poor staining quality, high background, etc.

P06	Information Customer Request	Request from the customer for information on non-performance related issues
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Code P06 Information Customer Request, is to be used when reporting a customer request for information. Typically this would be for specific assay related information, e.g. method sheets, method comparisons, together with information requests for general application or patient sample related advice and assistance.

Problem Code Expanded Definition continued

P07	Labelling / Documentation	Issues related to labelling / documentation of applications related products e.g. bar codes package inserts etc
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Code P07 Labelling / Documentation, is to be used to report customer issues relating to product documentation. Typically this would be to request clarification / explanation of package inserts, product labeling, or assistance with product barcoding.

P08	Packaging	Issues related to the packaging of products supplied by Roche
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Code P08 Packaging, is to be used to record all issues related to product packaging . Typically this would be where the product or packaging has been damaged in transit, or where product components are missing or incorrect.

P10	Shipping / Delivery	Issues related to product logistical topics, e.g. product availability
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Code P10 Shipping / Delivery, is to be used to record issues related to product delivery. Typically this would be to report incorrect delivery (product or quantity), or to request information regarding product availability and backorders.

P14	No problem found	No problems found
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Code P14 No problem found, is to be used when a reported application problem could not be found or reproduced.

P97	Empty Field	for internal data processing, not to be used in Clarify
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Code P97 Empty Field. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.
A Problem Category Code will be set to P97 Empty Field if the respective code field does not contain any information.

Problem Code Expanded Definition continued

P98	Not Global	for internal data processing, not to be used in Clarify
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Code P98 Not Global. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

A Problem Category Code will be set to P98 Not Global if the coded information received is not available in the list of global codes

P99	Not Applicable	for internal data processing, not to be used in Clarify
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Code P99 Not Applicable. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

A Problem Category Code will be set to P99 Not Applicable if

- the current code setting is P00 Please Specify and
- a valid and released Instrument Function Code or IT Category Code is used in this case (problem is described with generic HW/SW or IT product codes)

Cause Code Expanded Definition

C00	Please Specify	Default selection in Clarify
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Code C00 Please Specify. This code must not be used in a problem description visits (see above list of activities)! It is only available as a default code prior to selecting the actual cause code.

C01	Customer Technique / Handling	Issues related to customer or laboratory personal proficiency
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Code C01 Customer Technique / Handling, to be used to define problems caused by laboratory personnel. Typically this would be misuse of the product or problems associated with handling or storage of the product or associated samples, consumables, or accessories.

C02	Product Does Not Meet Customer Expectations	Product is within Roche published specification, but the customer expectation is not met
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Code C02 Product Does Not Meet Customer Expectations, to be used to record customer dissatisfaction with the product, although the product specification is fulfilled. Typically this will be a performance, quality or quantity related issue.

C03	Non-Roche Product	Failure of or caused by a non-Roche product used in combination with a Roche supplied product
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Code C03 Non-Roche product, to be used to define problems caused by the use of a non-Roche product. In addition to problems caused by the use of non-Roche instruments, reagents, controls and calibrators, this code also covers the use of non-Roche consumables and accessories.

C04	Patient Sample	Issues or problems related to measurements and or handling of patient samples
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Code C04 Patient Sample, to be used to define problems caused by the handling, storage, condition, or analyzing process of patient samples.

C05	External Control / Survey Sample	Issues related to measurements / handling / storage of external controls or survey control samples
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Code C05 External Control / Survey Sample, to be used to define problems caused by external controls or survey samples, typically unexpected assay results and poor correlation with other controls and calibrators.

Cause Code Expanded Definition Continued

C06	Outdated Assay Calibration	Issues related to an inaccurate or invalid calibration curve
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Code C06 Outdated Assay Calibration, to be used to identify problems caused by the use of an outdated calibration curve. Typically this would be used where the customer reports assay inaccuracy or linearity issues.

C07	Method Comparison	Request for assistance with method comparisons
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Code C07 Method Comparison, to be used either to define the cause of assay performance issues, or to record requests for assistance / advice with method comparison.

C08	Product Configuration Issue	Problems related to product design or manufacture
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Code C08 Product Configuration Issue, used to record causes of problems associated with assay performance, relating to the manufacture or content / formulation of the product.

C09	Shipment Error	Problems relating to the product integrity due to shipping errors
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Code C09 Shipment Error, used to report cause of problems associated with product shipment, typically damage to products due to mishandling or incorrect storage of the product during shipment to the customer site.

C10	Storage	Problems relating to product integrity due to storage on customer site
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Code C10 Storage, used to record causes of problems associated with the incorrect handling or storage of products on the customer site, typically products stored at incorrect temperature or stored in such a way that the product may have been damaged.

C11	Wrong Software / Assay Protocol	Issues related to incompatibility of assay protocols or software
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Code C11 Wrong Software / Assay Protocol, used to define causes of assay performance problems. Typically this would be to record the use of an incorrect or out of date analysis protocol or method.

Cause Code Expanded Definition Continued

C12	No cause found	No cause found, e.g. problem could not be reproduced or verified
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Code C12 No cause found, to be used with Problem Category code P14 (No problem found), when a reported application problem could not be reproduced or verified.

C13	Code Identification Missing / Unreadable / Incorrect	Issues related to the inability of analytical systems to recognize machine readable codes
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Code C13 Code Identification Missing / Unreadable / Incorrect, used to define the cause of a problem associated with the inability of an instrument to read or interpret machine-coded instructions, typically barcoded or optical-coded instructions.

C14	Label Missing / Unreadable / Incorrect	Issues related to readability / availability / accuracy of product labelling
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Code C14 Label Missing / Unreadable / Incorrect, used to define the cause of a problem associated with either the availability or legibility of the product instructions. Typically this would be where a product label is missing, or damaged in such a way as to make the label unreadable.

C15	Package Insert / Roche Documentation	Issues concerning Roche supplied product documentation and or package inserts
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Code C15 Package Insert / Roche Documentation, used to record causes of problems associated with product instructions, inserts or documentation, typically used where the product instructions are inaccurate, misleading, or missing.

C16	Backorder / Product Availability	Issues regarding non-availability or back-order delivery of Roche supplied products
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Code C16 Backorder / Product Availability, used to record causes of problems associated with shipping or delivery of products, typically where part order shipments have been made, or where product non-availability advice has been requested.

C17	Late / Wrong Delivery	Issues regarding timing or incorrect delivery of Roche supplied products
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Code C17 Late / Wrong Delivery, used to record causes of problems associated with incorrect delivery, typically late delivery or wrong product or quantity delivered.

Cause Code Expanded Definition Continued

C18	Component Missing / Wrong / Damaged	Problems related to package contents of Roche supplied products
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Code C18 Component Missing / Wrong / Damaged, used to define causes of problems associated with missing or damaged contents of a product. Typically this would be used where the actual delivery is correct but, part of the product is damaged, incorrect, or has not been shipped.

C20	Package Integrity	Issues related to internal or external packaging of Roche supplied products
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Code C20 Package Integrity, used to record causes of problems associated with the packaging of products. Typically this would be where the product has been delivered to the customer in a damaged condition due to inappropriate handling or poor quality of the product packaging.

C23	Product Introduction / New Product / Version Change	Issues or issues related to new product introduction or version changes
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Code C23 Product Introduction / New Product / Version Change, used to record cases related to new product introduction or version changes. Typically this would be to record requests for new product instructions or new product availability.

C24	Environmental	Issues related to the laboratory environment effecting assay results e.g. room temperature, water quality etc
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Code C24 Environment, used to record causes of problems associated with environmental conditions. Typically this would be where the laboratory room temperature, water quality, air quality, main power supplies etc. directly effect the analytical performance of the product.

C97	Empty Field	for internal data processing, not to be used in Clarify
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Code C97 Empty Field. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Application Cause Code will be set to C97 Empty Field if the respective code field does not contain any information.

Cause Code Expanded Definition Continued

C98	Not Global	for internal data processing, not to be used in Clarify
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Code C98 Not Global. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Application Cause Code will be set to C98 Not Global if the coded information received is not available in the list of global codes

C99	Not Applicable	for internal data processing, not to be used in Clarify
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Code C99 Not Applicable. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Application Cause Code will be set to C99 Not Applicable if

- the current code setting is C00 Please Specify and
- a valid and released Instrument Cause Code or IT Cause Code is used in this case (problem is described with generic HW/SW or IT product codes)

Fix Code Expanded Definition

X00	Please Specify	Default selection in Clarify
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Code X00 Please Specify. This code must not be used in a problem description visits (see above list of activities)! It is only available as a default code prior to selecting the actual fix code.

X01	Application Loaded / Updated	Customer or Roche representative update of specific application parameters
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Code X01 Application Loaded / Updated, used to report a fix made by either reloading existing application software / application instructions, or by loading new / updated application parameters. Application loaded / updated fix could be achieved by verbal instructions to customer, by remote connection, or an on-site visit from a Roche representative.

X02	Product Bulletin / Customer Letter	Forward published / formal information to customer in response to their call
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Code X02 Product Bulletin / Customer Letter, used to record a fix made by sending published information to the customer. This information can be in the form of a formal product bulletin, customer letter, news letter, marketing letter, etc. Communication can be via e-mail, mail, or fax.

X03	Customer Training	Training to resolve a specific customer issue, either on site, by telephone or by remote diagnostics
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Code X03 Customer Training, used to record a fix made by providing customer training to overcome a specific problem or difficulty. This training could be in the form of product training, methodology training, or instructions on laboratory techniques, etc. Training can take place on site, by remote diagnostics, by mail, or by telephone.

X04	Maintenance / Cleaning / Lubricating	Resolving the customer problem by giving guidance / advice on maintenance, cleaning or lubricating
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Code X04 Maintenance / Cleaning / Lubricating, used to record a fix made by guiding the customer through a first line service cleaning or maintenance operation. Typically this could take the form of either a mechanical cleaning and lubricating process, or a fluidic cleaning and flushing procedure.

Fix Code Expanded Definition Continued

X05	No Fix	Unable to resolve problem or issue, or unable to replicate problem
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Code X05 No Fix, used to record that the customer support desk was either unable to fix the problem and that the case has been forwarded to specialist personnel for further investigation; or that the problem could not be repeated and is pending further developments.

X06	Product Replacement	Send replacement product e.g. Reagent, consumable, spare part/CC
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X06 Product Replacement, used to record a fix made by replacing the defective product. This could take the form of sending replacement reagents, controls, calibrators, consumables, spare parts, etc, or the replacement and return for repair of a complete instrument.

X07	Provide Documentation	Provide product specific documentation e.g. package insert, bar code etc
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Code X07 Provide documentation, used to record a fix made by forwarding specific product documentation, e.g. package inserts to the customer. Communication can take the form of e-mail, mail, or fax.

X08	Provide Information	Provide informal advice or information on customer request
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Code X08 Provide information, used to record a fix made by providing information or advice to the customer. Typically this could be in the form of product operating tip's and techniques, or alternatively in the form of externally/ internally published methods and applications.

X09	Provide Materials	Provide materials, Roche or non-Roche for evaluation / trial / customer use
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Code X09 Provide Materials, used to record a materials forwarding activity, typically to provide reagents, controls, calibrators, etc for evaluation or trial.

Fix Code Expanded Definition Continued

X10	Recalibrate / Readjust	Resolving the customer problem by giving guidance / advice through recalibration or readjustment procedures
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Code X10 Recalibrate / Readjust, use to record a fix made by leading the customer through a calibration or adjustment procedure. Typically this could take the form of either a mechanical adjustment procedure, e.g. adjusting tip heights, or an application procedure to recalibrate a new standard curve.

X11	Repair	Dispatch to Field Engineering
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Code X11 Repair, used to record that the help desk did not find a fix and that the case has been transferred to engineering dispatch for further field action.

X12	Repeat / Re-run	Advise or guide customer through repeat / rerun procedure
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Code X12 Repeat / Re-run, used to record that a fix done by assisting the customer through a repeat or re-run of the assay, and that on completion of the re-run, the customer was satisfied that the problem had been resolved.

X97	Empty Field	for internal data processing, not to be used in Clarify
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Code PX97 Empty Field. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Application Fix Code will be set to X97 Empty Field if the respective code field does not contain any information.

X98	Not Global	for internal data processing, not to be used in Clarify
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Code X98 Not Global. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Application Fix Code will be set to X98 Not Global if the coded information received is not available in the list of global codes

Fix Code Expanded Definition Continued

X99	Not Applicable	for internal data processing, not to be used in Clarify
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Code X99 Not Applicable. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Application Fix Code will be set to X99 Not Applicable if

- the current code setting is X00 Please Specify and
- a valid and released Instrument Remedial Code or IT Remedial Code is used in this case (problem is described with generic HW/SW or IT product codes)