Predictive Health Notification Alinity I Optics Dark Count

ALINITY ci Immunoassay Analyzer

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PHN - Alinity IA Optics Dark Count Spec Sheet for Apollo

References

APLM ID D000039774/A Prognostic Health Notification for Alinity I Optics Dark Counts

Summary

To implement a Predictive Health Notification (PHN) for Alinity-i Analyzers that will detect degrading Background Read performance before the customer begins experiencing an increase in Error: 1401 Unable to process test, background read failure.

PHN Descriptor	Alinity IA Optics Dark Count
PHN Experience Code / Name	CCA1 PHN_Alinity_IA; PHN_Optics_IA; Dark Counts
PHN KM Article Number/ Name	K07342335 PHN_Alinity IA: Optics Dark Count
Service Level	2- Advanced Service
Always On Package	Always On 01DP5- 01, 02, 03, 09, 80, 83, 84, 89
IDA Table	IDAQOWNER.ICQ_RESULTS
IDA Table Fields	MODULESN, INTEGRATEDDARKCOUNT, TESTID, LODGATE_LOCAL
Analysis Frequency	Daily
Data Required	Previous 1 day
Data Aggregation	None
Run Time Estimate	7 seconds (1 day, 20 instruments, 7,732 rows, 2 algorithm flags)
Flag Criteria	N unique TESTIDs >= 10 and INTEGRATEDDARKCOUNT Maximum >= 543 and INTEGRATEDDARKCOUNT Standard Deviation >= 110
Probable Failure Modes	Salt buildup in the process path from leaking wash zones or trigger manifold. Light leakage due to loose covers, diverters or shutter movement problems.
Suppression Experience Codes	Z1OP, Z1OR, FAAA, FAAB, FAA1, FAC1
Applicable Work Done Codes (WDC)	FA3*: Optics CMIA Background/ Stray light FAG*: Optics CMIA Debris/dirty FB3*: Optics Reader Shutter Background FBG*: Optics Reader Shutter Dirty

Data Processing Steps

Data Processing Steps	
1	Query all data from the previous day for each instrument (IDA Table: IDAQOWNER.ICQ_RESULTS).
2	Exclude tests where INTEGRATEDDARKCOUNT is missing.
3	Exclude instruments where the number of unique TESTIDs is less than 10.
4	Summarize the data by calculating the INTEGRATEDDARKCOUNT maximum and standard deviation by instrument.
5	Flag any instrument where the number of unique TESTIDs is greater than or equal to 10, and the INTEGRATEDDARK COUNT maximum is greater than or equal to 543, and the INTEGRATEDDARKCOUNT standard deviation is greater than or equal to 110.

APPENDIX 1: CCA1 AI Dark Count

Algorithm Code

```
SELECT
        evals.MODULESN
FROM
        (SELECT
                R.MODULESN,
                MAX(R.INTEGRATEDDARKCOUNT) AS MAX_IDC,
                STDDEV(R.INTEGRATEDDARKCOUNT) AS SD_IDC,
                COUNT(DISTINCT(R.TESTID)) AS NUM_TESTID
        FROM
                IDAQOWNER.ICQ_RESULTS R
        WHERE
                R.LOGDATE_LOCAL >= TRUNC(SYSDATE) - 1
                AND R.LOGDATE_LOCAL < TRUNC(SYSDATE)
                AND R.INTEGRATEDDARKCOUNT IS NOT NULL
        GROUP BY
                R.MODULESN
        ORDER BY
                R.MODULESN
        ) evals
WHERE
        evals.MAX_IDC >= 543
        AND evals.SD_IDC >= 110
        AND evals.NUM_TESTID >= 10
```

Apollo Algorithm Details

(* is Mandatory)

Apollo Details	
Algorithm ID *	Alinity IA Dark Count
Algorithm Name *	Alinity IA Optics Dark Count
Algorithm Description *	To detect degrading Background Read performance before the customer begins experiencing an increase in Error: 1401 Unable to process test, background read failure.
Product Family *	Alinity IA
Algorithm Group *	Alinity Optics
Functional Area	N/A
Algorithm Category 1	N/A
Algorithm Category 2	N/A
Algorithm Category 3	N/A
Remaining Useful Life Value	7
Remaining Useful Life Unit	Day
Keep Results Num Days	14
Routine Details	
Routine Source	Define New Routine
Reusable Routines	N/A
Routine Type	Oracle Procedure
Run Mode	Batch
Routine Invoke Command	PHM_ICQ_DarkCount_PROC
Status	Enable
ODS Routine Details	

ODS Routine Name	PHM_ODS_ICQ_RESULTS_PROC
Predictive Health Notification Details	
PHN Code	PHN_Alinity IA_CCA1
Issue Description (Use Algorithm Name)	
Experience Code	CCA1
Knowledge Management DB Articles	
KM Article ID	K07342335
KM Article	PHN_Alinity IA: Optics Dark Count
Parameters	
Parameter Group Name	ICQ_DARKCOUNT
Parameter Name	**Parameter Values**
IHN_LEVEL3_DESC	Alinity IA Optics Dark Count
INTEGRATEDDARKCOUNT_MAX	543
INTEGRATEDDARKCOUNT_SD	110
TESTID	10
THRESHOLDS_COUNT	1
THRESHOLD DESCRIPTION	Alinity IA Optics Dark Count
Chart Details	
Chart Title	Alinity IA Optics Dark Count
Chart Type	Line Chart
Chart Threshold Parameter	ICQ DARKCOUNT – Thresholds_Count
Group ID	Group 7
Chart X Axis Name	Date
Chart Y Axis Name	Threshold Count

APPENDIX 2: Algorithm Understanding Check – Algorithm Developer to Predictive Health Monitoring (PHM) Specialist Transition

Data Set Description

The data set for this understanding check was retrieved from the ICQOWNER.ICQ_RESULTS table within the BSQD1I database. Data was collected for all instruments between December, 1 2016 and February 28, 2017, inclusive. Data collection was limited to the SERIALNUMBER, DATETIMESTAMP, INTEGRATEDDARKCOUNT, and TESTID fields.

Data Set Retrieval

The following SQL code was used to retrieve the data set:

```sql
SELECT
        R.SERIALNUMBER,
        R.DATETIMESTAMP,
        R.INTEGRATEDDARKCOUNT,
        R.TESTID
FROM
        ICQOWNER.ODR_RESULTSICQ R
WHERE
        TRUNC(R.DATETIMESTAMP) >= TO_DATE('12/01/2016 12:00:00 AM', 'mm/dd/yyyy hh:mi:ss am')
        AND TRUNC(R.DATETIMESTAMP) < TO_DATE('03/01/2017 12:00:00 AM', 'mm/dd/yyyy hh:mi:ss am')
```

Algorithm Developer Analysis

The following JMP script (JMP version 12.1.0) was used by the Algorithm Developer to analyze the data set and flag algorithm violations:

```
New SQL Query(
Connection(
"ODBC:DSN=BSQD1I;UID=birchkm;PWD=%_PWD_%;DBQ=BSQD1I;DBA=W;APA=T;EXC=F;FEN=T;QTO=T;FRC=10;FDL=10;LOB=T;RST=T;BTD=F;
BNF=F;BAM=IfAllSuccessful;NUM=NLS;DPM=F;MTS=T;MDI=F;CSR=F;FWC=F;FBS=100000000;TLO=O;MLD=0;ODA=F;"
),
QueryName( "ODR_RESULTSICQ" ),
Select(
        Column( "MODULESNDRM", "t2" ),
        Column( "SERIALNUMBER", "t2" ),
        Column( "TESTID", "t2" ),
        Column(
                "DATETIMESTAMP",
                "t2",
                Numeric Format( "m/d/y h:m:s", "0", "NO", "" )
        ),
        Column( "INTEGRATEDDARKCOUNT", "t2" )
),
From( Table( "ODR_RESULTSICQ", Schema( "ICQOWNER" ), Alias( "t2" ) ) ),
Where(
        Is Not Null(
                Column( "INTEGRATEDDARKCOUNT", "t2" ),
                UI( NullTest( Base( "Continuous" ) ) )
        ) & GE(
                Column(
                        "DATETIMESTAMP",
                        "t2",
                        Numeric Format( "m/d/y h:m:s", "0", "NO", "" )
                ),
                3563395200,
                UI( Comparison( Base( "Continuous" ) ) )
        ) & LT(
                Column(
                        "DATETIMESTAMP",
                        "t2",
                        Numeric Format( "m/d/y h:m:s", "0", "NO", "" )
                ),
                3571171200,
                UI( Comparison( Base( "Continuous" ) ) )
        )
)
) << Run
```

```
Data Table( "ODR_RESULTSICQ" ) << Summary(
        Group( :MODULESNDRM, :SERIALNUMBER, :Day ),
        N( :TESTID ),
        Max( :INTEGRATEDDARKCOUNT ),
        Std Dev( :INTEGRATEDDARKCOUNT ),
        Freq( "None" ),
        Weight( "None" )
        );

New Column( "Flag Yes/No",
        Numeric,
        "Nominal",
        Format( "Best", 12 ),
        Formula(
                If(
                        :Name( "N(TESTID)" ) >= 10 & :Name( "Max(INTEGRATEDDARKCOUNT)" ) >= 543 &
                        :Name( "Std Dev(INTEGRATEDDARKCOUNT)" ) >= 110,
                        1,
                        0
                )
        ),
        Value Labels( {0 = "No", 1 = "Yes"} ),
        Use Value Labels( 1 )
);
```

PHM Specialist Analysis

The following SQL code was used by the PHM Specialist to analyze the data set and flag algorithm violations:

```
SELECT
        evals.SERIALNUMBER,
        evals.DAY,
        evals.MAX_IDC,
        evals.SD_IDC,
        evals.NUM_TESTID
FROM
        (SELECT
                R.SERIALNUMBER,
                TRUNC(R.DATETIMESTAMP) AS DAY,
                MAX(R.INTEGRATEDDARKCOUNT) AS MAX_IDC,
                STDDEV(R.INTEGRATEDDARKCOUNT) AS SD_IDC,
                COUNT(DISTINCT(R.TESTID)) AS NUM_TESTID
        FROM
                ICQOWNER.ODR_RESULTSICQ R
        WHERE
                TRUNC(R.DATETIMESTAMP) >= TO_DATE('12/01/2016 12:00:00 AM', 'mm/dd/yyyy hh:mi:ss am')
                AND TRUNC(R.DATETIMESTAMP) < TO_DATE('03/01/2017 12:00:00 AM', 'mm/dd/yyyy hh:mi:ss am')
                AND R.INTEGRATEDDARKCOUNT IS NOT NULL
        GROUP BY
                R.SERIALNUMBER,
                TRUNC(R.DATETIMESTAMP)
        ORDER BY
                R.SERIALNUMBER,
                TRUNC(R.DATETIMESTAMP)
        ) evals
WHERE
        evals.MAX_IDC >= 543
        AND evals.SD_IDC >= 110
        AND evals.NUM_TESTID >= 10
```

Algorithm Developer Analysis Output

The following 25 instruments (SERIALNUMBER) were identified as violating the algorithm by the Algorithm Developer:

	SERIALNUMBER	Day	N(TESTID)	Max(INTEGRATEDDARKCOUNT)	Std Dev(INTEGRATEDDARKCOUNT)
1	AI01004	12/16/2016	50	3192	699.963770491016
2	AI01013	01/06/2017	49	1319	296.945421472252
3	AI01015	01/10/2017	49	1312	278.733444949352
4	ia00001	01/11/2017	69	1341	337.474743458371
5	ia00001	01/12/2017	122	710	155.005035952298
6	IM00121	12/15/2016	421	8241	2300.70567298871
7	IM00123	12/09/2016	129	22809	4359.60031943892
8	IM00127	12/01/2016	217	640	132.1348914719
9	IM00127	12/07/2016	302	627	133.663277252922
10	IM00127	12/08/2016	427	630	112.138234267209
11	IM00127	12/12/2016	175	579	111.764398572074
12	IM00127	12/14/2016	26	637	148.306916691237
13	IM00127	12/19/2016	14	591	144.238146331485
14	IM00127	12/20/2016	30	581	155.621486711947
15	IM00127	01/05/2017	59	867	205.239290997747
16	IM00127	01/20/2017	88	682	111.338432148806
17	IV00021	01/31/2017	201	1856	290.742671010412
18	Qi00115	02/22/2017	24	21061	2187.99910206841
19	Qi00118	12/15/2016	80	774	138.841716180328
20	Qi00120	12/07/2016	58	1309	215.279514138019
21	Qi00127	02/08/2017	99	593	118.406715511803
22	Qi00127	02/10/2017	25	543	110.248764165409
23	Qi00138	12/23/2016	42	7375	2467.72298473399
24	Qi00139	01/05/2017	29	620	120.526308883185
25	Qi00147	02/22/2017	35	14905	6805.12668915592

PHM Specialist Analysis Output

The following 25 instruments (SERIALNUMBER) were identified as violating the algorithm by the PHM Specialist:

	SERIALNUMBER	DAY	MAX_IDC	SD_IDC	NUM_TESTID
1	AI01004	12/16/2016 12:00:00 AM	3192	699.963770491016	50
2	AI01013	01/06/2017 12:00:00 AM	1319	296.945421472252	49
3	AI01015	01/10/2017 12:00:00 AM	1312	278.733444949352	49
4	ia00001	01/11/2017 12:00:00 AM	1341	337.474743458371	69
5	ia00001	01/12/2017 12:00:00 AM	710	155.005035952298	122
6	IM00121	12/15/2016 12:00:00 AM	8241	2300.70567298871	421
7	IM00123	12/09/2016 12:00:00 AM	22809	4359.60031943892	129
8	IM00127	12/01/2016 12:00:00 AM	640	132.1348914719	217
9	IM00127	12/07/2016 12:00:00 AM	627	133.663277252922	302
10	IM00127	12/08/2016 12:00:00 AM	630	112.138234267209	427
11	IM00127	12/12/2016 12:00:00 AM	579	111.764398572074	175
12	IM00127	12/14/2016 12:00:00 AM	637	148.306916691237	26
13	IM00127	12/19/2016 12:00:00 AM	591	144.238146331485	14
14	IM00127	12/20/2016 12:00:00 AM	581	155.621486711947	30
15	IM00127	01/05/2017 12:00:00 AM	867	205.239290997747	59
16	IM00127	01/20/2017 12:00:00 AM	682	111.338432148806	88
17	IV00021	01/31/2017 12:00:00 AM	1856	290.742671010412	201
18	Qi00115	02/22/2017 12:00:00 AM	21061	2187.99910206841	24
19	Qi00118	12/15/2016 12:00:00 AM	774	138.841716180328	80
20	Qi00120	12/07/2016 12:00:00 AM	1309	215.279514138019	58
21	Qi00127	02/08/2017 12:00:00 AM	593	118.406715511803	99
22	Qi00127	02/10/2017 12:00:00 AM	543	110.248764165409	25
23	Qi00138	12/23/2016 12:00:00 AM	7375	2467.72298473399	42
24	Qi00139	01/05/2017 12:00:00 AM	620	120.526308883185	29
25	Qi00147	02/22/2017 12:00:00 AM	14905	6805.12668915592	35

Algorithm Developer & PHM Specialist Output Comparison

Total # of Unique Instrument-Days Tested	Total # of Algorithm Developer Flags	Total # of PHM Specialist Flags	Total # of Matched Flags (Algorithm Developer vs. PHM Specialist)
2,679	25	25	25

Understanding Check Summary

Based on the outputs from both the Algorithm Developer and PHM Specialist, the PHM Specialist's understanding of the delivered algorithm is confirmed. Both the Algorithm Developer and PHM Specialist analyzed the same data set and got the same results. In particular, the SERIALNUMBER and Day/DAY fields matched for all 25

instrument-day (SERIALNUMBER- Day/DAY) combinations. This means that both the Algorithm Developer and PHM Specialist flagged the same 25 algorithm violations within the given data set. Furthermore, there were no mismatches between the output from the Algorithm Developer and the output from the PHM Specialist.
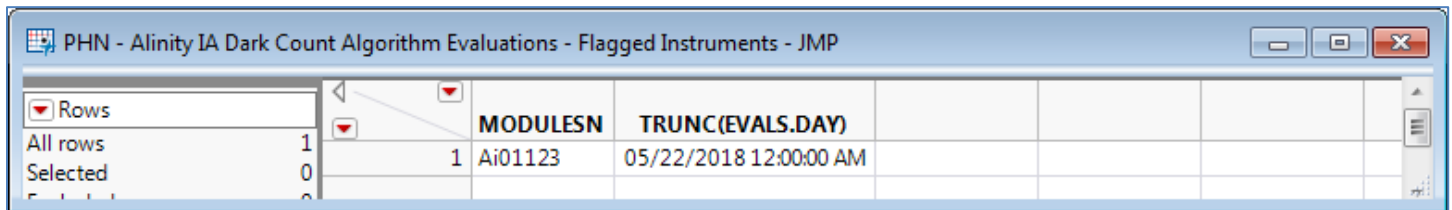
APPENDIX 3: Algorithm Transition to Apollo – PHM Specialist to Apollo Developer

Data Set Description

The data set for this transition was retrieved from the IDAQOWNER.ICQ_RESULTS table within the DABBTO database. Data was collected for all available instruments between May, 21 2018 and May 23, 2018, inclusive.
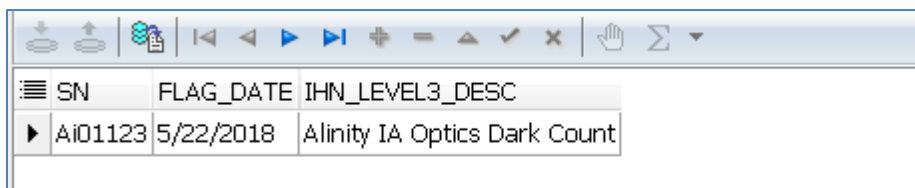
PHM Specialist Analysis Output

The following instrument-day (MODULESN-TRUNC(EVALS.DAY)) was identified as violating the algorithm by the PHM Specialist:

Apollo Developer Analysis Output

The following instrument-day (SN-FLAG_DATE) was identified as violating the algorithm by the Apollo Developer:

Algorithm Transition Summary

Based on the outputs from both the Apollo Developer and PHM Specialist, the Apollo Developer's understanding of the delivered algorithm is confirmed. Both the Apollo Developer and PHM Specialist analyzed the same data set and got the same results. In particular, the MODULESN/SN and TRUNC(EVALS.DAY)/FLAG_DATE fields matched. This means that both the Apollo Developer and PHM Specialist flagged the same algorithm violation within the given data set.