Integrated Analysis Plan

Clinical Study Protocol Identification No.	MS200527-0074
Title	A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of Evobrutinib Compared with an Interferon Beta 1a (Avonex®), in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety
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Investigational Medicinal Product(s)	Evobrutinib
Clinical Study Protocol Version	05 September 2019 / Version 2.0 (18 July 2019 / Version 1.1 US only)
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Approval Page

Integrated Analysis Plan: MS200527-0074

A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of Evobrutinib Compared with an Interferon Beta 1a (Avonex®), in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety

Approval of the Integrated Analysis Plan (IAP) by all Merck Data Analysis Responsible has to be documented within Electronic Document Management System (EDMS) via eSignature. With the approval, the Merck responsible for each of the analysis also takes responsibility that all reviewers' comments are addressed adequately.

By using eSignature, the signature will appear at the end of the document.

1 Table of Contents

Table of In-Text Tables

2 List of Abbreviations and Definition of Terms

CCI	[redacted]
AE	Adverse Event
AESI	Adverse Event of Special Interest
ALT	Alanine aminotransferase
ARR	Annualized Relapse Rate
AST	Aspartate aminotransferase
AUC	Area under the curve
BID	Twice per day
BMI	Body mass index
BTK	Bruton's Tyrosine Kinase
CCI	[redacted]
CDP	Confirmed Disability Progression
CFB	Change from Baseline
CL/F	Apparent plasma clearance following oral administration
C_{max}	Maximum plasma concentration
(e)CRF	(electronic) Case Report Form
CSR	Clinical Study Report
CUA	Combined Unique Active
DBP	Diastolic Blood Pressure
DRM	Data Review Meeting
ECG	Electrocardiogram
EDMS	Electronic Document Management System
EDSS	Expanded Disability Status Scale
EEA	European Economic Area
FA	Final Analysis
HRQOL	Health Related Quality of Life
CCI	[redacted]
IA	Interim Analysis
IAP	Integrated Analysis Plan
IDMC	Independent Data Monitoring Committee

Ig	Immunoglobulin
LFT	Liver Function Tests
Mean	Arithmetic Mean
MedDRA	Medical Dictionary for Regulatory Activities
MS	Multiple Sclerosis
NA	Not Applicable
NCI-CTCAE	National Cancer Institute – Common Terminology Criteria for Adverse Events
CCI	[redacted]
OLE	Open Label Extension
CCI	[redacted]
PF	Physical Function
CCI	[redacted]
PROMIS	Patient Reported Outcomes Measurement Information System
PT	Preferred Term
RMS	Relapsing Multiple Sclerosis
RRMS	Relapsing-remitting Multiple Sclerosis
SAE	Serious Adverse Event
SAF	Safety Analysis Set
SAS	Statistical Analysis System
SBP	Systolic Blood Pressure
SCR	Screening Analysis Population
CCI	[redacted]
SDTM	Study Data Tabulation Model
CCI	[redacted]
SFU	Safety Follow-up
SOC	System Organ Class
SPMS	Secondary Progressive Multiple Sclerosis
SSR	Sample Size Re-estimation
CCI	[redacted]
TEAE	Treatment-Emergent Adverse Event
V_z/F	Apparent volume of distribution
WHO-DD	World Health Organization Drug Dictionary

3 Modification History

Unique Identifier for Version	Date of IAP Version	Author	Changes from the Previous Version
1.0	28May2020	PPD	Initial Version

4 Purpose of the Integrated Analysis Plan

The purpose of this IAP is to document technical and detailed specifications for the final analysis of data collected for protocol MS200527-0074. Results of the analyses described in this IAP will be included in the synoptic Clinical Study Report (CSR). Any post-hoc, or unplanned analyses performed to provide results for inclusion in the CSR but not identified in this prospective IAP will be identified in the CSR.

5 Objectives and Endpoints

Objectives and endpoints are summarized in Table 1.

Table 1: Objective and Endpoints

Objectives	Endpoints (Outcome Measures)	IAP Section
Primary		
To demonstrate superior efficacy with evobrutinib compared to Avonex in terms of annualized relapse rate (ARR)	ARR based on qualified relapses at Week 96 in participants with relapsing multiple sclerosis (RMS)	NA
Secondary		
To demonstrate the efficacy of evobrutinib relative to that of Avonex on disability progression	• Time to first occurrence of 12-week confirmed Expanded Disability Status Scale (EDSS) progression over 96 weeks • Time to first occurrence of 24-week confirmed EDSS progression over 96 weeks	NA
To demonstrate the efficacy of evobrutinib relative to that of Avonex on patient reported symptoms and functional status	• Change from Baseline (CFB) in Patient Reported Outcomes Measurement Information System [PROMIS] Physical Function (PF) score at 96 weeks • CFB in PROMIS Fatigue score at 96 weeks	NA
To demonstrate the efficacy of evobrutinib relative to that of Avonex on magnetic resonance imaging (MRI) lesion parameters	• Total number of T1 Gd+ lesions based on assessments at Week 24, Week 48, and Week 96 • Total number of new or enlarging T2 lesions based on assessments at Week 24, Week 48, and Week 96	NA
To characterize the safety and tolerability of evobrutinib.	Safety as assessed by the nature, severity, and occurrence of adverse events (AEs) and adverse events of special interest (AESIs); vital signs; electrocardiograms (ECGs); absolute concentrations and change from Baseline in immunoglobulin (Ig) levels; and clinical laboratory safety parameters up to Week 108	15


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Open Label Extension (OLE) Period		
To evaluate the long-term safety, efficacy, and HRQoL of evobrutinib for an additional 144 weeks	• Efficacy and HRQoL endpoints at Weeks 48, 96, and 144 ○ ARR, based on protocol-defined qualified relapses ○ Change from Baseline in PROMIS PF score ○ Change from Baseline in PROMIS fatigue score ○ Change from Baseline in Medical Outcomes Study 36 Item Short Form Health Survey (SF-36v2) • Efficacy and HRQoL endpoints over 144 weeks ○ Time to first occurrence of 12-week confirmed EDSS progression over 144 weeks ○ Time to first occurrence of 24-week confirmed EDSS progression over 144 weeks ○ Time to first occurrence of 12-week confirmed PF deterioration compared to Baseline over 144 weeks • Efficacy endpoints at Weeks 24, 48, 96, and 144 ○ Total number of new or enlarging T2 lesions ○ Total number of T1 Gd+ lesions • Safety as assessed by the nature, severity, and occurrence of AEs and AESIs; vital signs; ECGs; absolute concentrations and change from Baseline in Ig levels; clinical laboratory safety parameters up to Week 144	NA

NA: Not applicable; see Section 7.

CCI

This IAP covers the final analysis of data after early database lock. See section 7.

7 Changes to the Planned Analyses in the Clinical Study Protocol

Following analysis of open label extension (OLE) data from the RMS phase 2 study (MS200527-0086), it was determined that a change in active comparator was warranted in the phase 3 RMS program comprised of trials MS200527-0073 and MS200527-0074. Consequently, trial MS200527-0074 was terminated early CCI . Only one subject was randomized/treated in this trial.

Due to early termination, changes to the Clinical Trial Protocol (CTP) statistical section (Section 9 "Statistical Considerations" Trial Protocol MS200527-0074) are required. None of the planned analyses described in Section 9 of this protocol will be performed and data collected on subjects will be listed only, after the database has been locked. The listings were chosen to satisfy the requirements of a Clinical Study Synopsis Report.

8 Analysis Populations and Subgroups

8.1 Definition of Analysis Populations

The analysis populations are specified in Table 2 below.

Table 2: Analysis Sets

Analysis Set	Description
Screening (SCR)	All participants, who provided informed consent, regardless of the participant's randomization and study intervention status in the study.
Safety (SAF)	All participants, who were administered any dose of any study intervention. Participants will be analyzed according to the actual treatment they receive. If a participant receives more than one study treatment, the participant will be classified according to the treatment he/she has been most exposed to.

The SAF analysis set will be the only population for reporting in this study.

As no efficacy analyses will be performed, neither a Full Analysis Set nor a Per Protocol Analysis Set will be defined. Similarly, no analysis sets need to be defined for analysis of HRQOL, CCI or CCI endpoints.

8.2 Subgroup Definition and Parameterization

Not applicable.

9 General Specifications for Data Analyses

This section describes any general specifications not included in subsequent sections.

Treatment groups and study intervention

Treatment groups in the double blind, double dummy period are defined as indicated in CCI

:

9.1 Definition of Baseline

For the purpose of statistical analysis, baseline is defined as the last non-missing measurement (including those collected at an Unscheduled visit) prior to the first dose of study. If baseline cannot be defined, then the baseline value will be treated as missing.

9.2 Study Day / Study Treatment Day

Study day is defined relative to the date of randomization. Treatment day is defined relative to the date of start of treatment.

The day before the start date of treatment is defined as treatment day -1, i.e., there is no treatment day zero.

9.3 Definition of Duration and 'time since' Variables

Duration will be calculated as the difference between start and stop dates plus 1 (eg, AE duration (days) = AE end date - AE start date + 1). Durations will be calculated only when both dates are available (imputed dates cannot be used for the duration computation) unless otherwise specified.

The time since an event will be calculated as:

- reference date minus date of event +1 (eg, days in study at onset of AE = AE start date - date of randomization + 1) if date of event is equal or greater than reference date

- reference date minus date of event (eg, days in study at onset of AE = AE start date - date of randomization) otherwise.

9.4 Conversion Factors

The following conversion factors will be used to convert days into months or years:
1 week = 7 days, 1 month = 30.4375 days, 1 year = 365.25 days.

9.5 Definition of Body Mass Index (BMI) (kg/m²)

BMI will be computed as weight / (height²), where weight is expressed in kg and height in m.

9.6 Repeated and Unscheduled Measurements

Repeated and unscheduled measurements are included in the listings.

9.7 Definition of On-treatment Period

On-treatment values are results of assessments done from the first study intervention administration on Day 1 until End of Study (completion or early termination).

9.8 Imputation of Missing Data

Presentation of missing data

In all participant data listings, partial dates, which are not to be imputed according to this IAP, will be presented using the format "_____YYYY". When presented, imputed dates will be flagged (ie, D for day, M for month).

In case of zero records available for presentation in a given listing, an empty output with a sentence stating that there are no data will be provided.

Handling of missing or partial adverse events dates

For defining the TEAE flag, missing or partial adverse event dates will be imputed as follows:

- In case the onset date is missing completely or missing partially but the onset month and year, or the onset year are equal to the start of study intervention, then the onset date will be replaced by the minimum of start of study intervention and AE resolution date.
- In all other cases the missing onset day or missing onset month will be replaced by 1.
- Incomplete stop dates will be replaced by the last day of the month (if day is missing only), if not resulting in a date later than the date of participant's death. In the latter case the date of death will be used to impute the incomplete stop date.

Imputed dates will be used for defining the TEAE flag only.

Handling of partially missing multiple sclerosis (MS) first attack or diagnosis date

For time since MS first attack or MS diagnosis, a missing onset day/month will be replaced by 1 for the duration derivation.

9.9 Software

All statistical analyses will be performed using SAS® (Statistical Analysis System, SAS-Institute, Cary, North Carolina Windows Version 9.4 or higher).

9.10 Unblinding

Details regarding the unblinding process are available in the unblinding plan (MS200527-0074_unblinding_plan_final_v1.0_19May2020.pdf).

10 Study Participants

The subsections in this section include specifications for reporting participant disposition and study treatment/study discontinuations. Additionally, procedures for reporting protocol deviations are provided.

10.1 Disposition of Participants and Discontinuations

Participants' information on informed consent, screening and randomization will be listed. Participants discontinued from treatment or study will be listed with their reason for withdrawal (from treatment or study).

10.2 Protocol Deviations / Exclusion from Analysis Populations

As no efficacy analysis sets are required for the primary analysis of this study, protocol deviations are not used to exclude subjects from an analysis set.

10.2.1 Important Protocol Deviations

Important protocol deviations are protocol deviations that might significantly affect the completeness, accuracy, and/or reliability of the study data or that might significantly affect a participant's rights, safety, or well-being. Important protocol deviations are defined in a separate document (latest version of MS200527-0074_List_of_IPDs).

All deviations will be identified by either site monitoring, medical review processes or programming and confirmed prior to or at the Data Review Meeting (DRM), which will occur before the database lock.

Important protocol deviations will be documented in Clinical Data Interchange Standards Consortium SDTM whether identified through sites monitoring or medical, and provided in a participant data listing.

10.2.2 Reasons Leading to the Exclusion from an Analysis Population

Not applicable.

11 Demographics and Other Baseline Characteristics

Demographics and baseline characteristics will be listed on SAF.

11.1 Demographics

- Demographic characteristics
  - Sex: male, female
  - Race: White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, Multiple (Combinations reported with '/'), Not collected at this site, Other
  - Ethnicity: Hispanic or Latino, Not Hispanic or Latino
  - Age (years) at informed consent: summary statistics
- Geographic Region: North America, Western Europe, Eastern Europe, ROW from IWRS
- European Economic Area (EEA)
- Baseline EDSS (<4.0, ≥4.0) from IWRS

Specifications for computation:

- Age (years):
  - (date of given informed consent - date of birth + 1) / 365.25
  - In case of missing day for date of birth, but month and year available:
    - For the derivation of age, the day of birth will be set to 1 and the formula above will be used
  - In case of missing month for at date of birth, but year available:
    - For the derivation of age, the day and the month of birth will be set to 1 and the formula above will be used

11.2 Other Baseline Characteristics

Information on MS baseline disease characteristics, based on data collected on Day 1 predose and during screening, will be listed:

- Type of MS, either relapsing-remitting MS (RRMS) or secondary progressive MS (SPMS)
- Conversion date from RRMS to SPMS (for participants with SPMS)

- Initial MS diagnosis date
- Time (years) since initial MS diagnosis date
- Time (years) since first attack
- System(s) affected by first attack
- Number of relapse(s) in the last two years
- Number of relapse(s) from last year
- Fulfills McDonald criteria 2017, fulfills 2017 and 2010 McDonald criteria
- Was there at least 1 Gadolinium positive T1 lesion within 6 months prior to randomization?

12 Previous or Concomitant Medications/Procedures

12.1 Previous or Concomitant Medications

The ATC-2nd level and PT will be tabulated as given from the World Health Organization Drug Dictionary (WHO-DD) current version. In case multiple ATCs are assigned to a drug, all ATC-2nd level will be used for reporting.

Previous or concomitant medications will be listed, based on "RELEVANT PREVIOUS MEDICATIONS" & "CONCOMITANT MEDICATIONS" eCRF pages. The WHO-DD version used will be indicated in footnote.

The definition of previous or concomitant medication is presented in Table 4:

Table 4: Definition of previous/concomitant medication

Treatment groups	Definition
CCI	**Previous medications** are medications, other than study interventions, which either: 1. started and stopped before first administration of any study intervention (Avonex or evobrutinib). 2. started prior to the first administration of study intervention (Avonex or evobrutinib) and are taken by participants on or after the first administration of study intervention (including safety follow-up (SFU) for early discontinued participants).
	Concomitant medications are medications, other than study interventions, which either: 1. started on or after the first administration of any study intervention (Avonex or evobrutinib). 2. started prior to the first administration of study intervention (Avonex or evobrutinib) and are taken by participants on or after the first administration of study intervention (including SFU for early discontinued participants).

Partial dates will be handled as follows:

- For previous medications, in case the date values will not allow a medication to be unequivocally allocated to previous medication, the medication will be considered as previous medication.
- For concomitant medications, in case the date values will not allow a medication to be unequivocally allocated to concomitant medication, the medication will be considered as concomitant medication.

12.2 Prior or Concurrent Procedures

Not applicable.

13 Study Treatment Exposure

Data will be listed by treatment group and participant on SAF.

13.1 Exposure Calculation

Dose interruptions/changes will not be considered in exposure calculation. Dose interruptions/changes with the associated reason will only be listed.

Details describing study therapy dosing and administration are provided in Table 5.

Treatment duration in weeks will be calculated according to the following formula:

$$Duration\ of\ Evobrutinib\ (weeks) = \frac{(date\ of\ last\ dose\ -\ date\ of\ first\ dose\ +\ 1)}{7}$$

$$Duration\ of\ Avonex\ (weeks) = \frac{(date\ of\ last\ dose\ -\ date\ of\ first\ dose\ +\ 7)}{7}$$

First dose refers to the first administration of any study intervention. Last dose refers to the last administration of any study intervention. Both dates of first and last dose will be retrieved from SDTM EC domain ["Evobrutinib / Placebo Administration Details" and "Avonex / Placebo Administration Details" eCRF pages].

Participant data listings:

Study drug administrations from the 2 eCRF pages will be listed by treatment group, and participant, with start/end dates of administration, and reason for dose change or no dose (if applicable). The duration of treatment will be reported for each participant.

14 Efficacy Analyses

As a synoptic CSR will be prepared and only 3 participants were randomized, efficacy data will not be reported.

15 Safety Analyses

The subsections in this section include specifications for summarizing safety endpoints that are common across clinical studies such as adverse events, laboratory tests and vital signs.

Safety listings will be presented on the SAF.

15.1 Adverse Events

All analyses described in this section will be based on TEAEs if not otherwise specified.

TEAEs will be defined as:

- AEs starting on or after first treatment administration of any study intervention (Avonex or evobrutinib) until safety follow-up (end of study),
- or if it was present prior to any study intervention administration but exacerbated after.

Any AE which started before study first treatment administration of any study intervention (Avonex or evobrutinib) but improved during treatment period until safety follow up (end of study) will not be counted as TEAE.

15.1.1 All Adverse Events

AEs will be coded according to the latest MedDRA version available at the time of analysis. The severity of AEs will be graded using NCI-CTCAE version 4.03 toxicity grades. AEs with missing classification concerning study intervention relationship will be considered related to the study intervention.

Participant data listings

TEAEs will be listed by treatment group and participant.

15.2 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

15.2.1 Deaths

Not applicable.

15.2.2 Serious Adverse Events

A participant listing of serious TEAEs will be provided.

15.2.3 Other Significant Adverse Events

The following events are defined as AEs of Special Interest (AESI):

- Liver AEs
    - Transaminase and bilirubin elevations, Hy's law cases
    - Hepatitis non-infectious
    - Hepatic failure, fibrosis and cirrhosis, and other liver damage-related conditions
    - Immune-medical hepatitis, alloimmune hepatitis, non-alcoholic fatty liver
- Severe Infections:
    - Serious AEs or Grade ≥ 3
    - Opportunistic infections Grade ≥ 3
- Amylase and Lipase elevations
    - Enzyme elevations Grade ≥ 3
    - Acute pancreatitis SMQ

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15.3 Clinical Laboratory Evaluation

The following laboratory parameters will be measured during the study as part of the safety evaluation:

- Hematology,

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- Urinalysis,
- Coagulation.

The clinical laboratory safety tests to be measured in this study are provided in the protocol (refer to Appendix 5 of the CTP). All available parameters from these 4 categories will be listed (refer to Appendix 18.2).

All laboratory data results will be presented using international system of units (SI).

Some laboratory results will be classified according to NCI-CTCAE Version 4.03. In case a laboratory parameter has bi-directional toxicities (e.g., Potassium) both directions will be presented for the given parameter (i.e., Potassium Low and Potassium High).

Laboratory results containing a modifier such as "<" or ">=" will be reported as collected in the database in participant data listings.

Participant data listings will be provided, with a flag for abnormal values, along with corresponding normal ranges:

- Laboratory gradable parameters part of NCI-CTCAE will be presented according to the categories based on normal ranges along with the grade. Abnormal values will be flagged according to the direction of toxicity (e.g., for a parameter such as Potassium Low, only values below the LLN will be flagged).
- Laboratory parameters that are not part of NCI-CTCAE will be presented according to the categories based on normal ranges: below normal limits (Low), within normal limits (Normal), and above normal limits (High). Values that are either above ULN or below LLN will be flagged.

In this study, clinically significant lab abnormalities were recorded as adverse events. In lieu of a listing of clinically significant lab abnormalities for each domain, the following by-participant lab value listings will be provided:

- Listing of Grade ≥ 3 hematology values
- Listing of Grade ≥ 3 biochemistry values or Grade ≥ 2 AST, ALT or Bilirubin.

15.4 Vital Signs

Vital signs (height (m), weight (kg), BMI (kg/m²), body temperature (°C), Systolic Blood Pressure (SBP) (mmHg), Diastolic Blood Pressure (DBP) (mmHg), respiratory rate (breaths/min) and pulse rate (beats/min)) will be listed by treatment group and visit.

15.5 12-Lead Electrocardiogram (ECG)

Listings of ECG quantitative values, results of ECG and rhythm results will be produced by intervention group, participant ID and visit/timepoint.

15.6 Immunoglobulin levels

Listing of absolute value and change from baseline in Immunoglobulin levels will be produced by intervention group, participant ID and visit/timepoint.

16 Analyses of Other Endpoints

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16.2 Pharmacodynamics

Not applicable.

16.3 Population PK/PD Modeling

Not applicable.

16.4 Patient Reported Outcomes

Not applicable.

17 References

Crowe BJ, Xia HA, Berlin JA, et al. Recommendations for safety planning, data collection, evaluation and reporting during drug, biologic and vaccine development: a report of the safety planning, evaluation, and reporting team. Clin Trials. 2009;6(5):430-40.

18 Appendices

18.1 CCI

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18.2 Laboratory Parameters to be Listed

Table 6: Laboratory Parameters to be Listed

	Names of Clinical Safety Laboratory Evaluations in Protocol Version 2.0, 05Sep2019 and Version 1.1, 18Jul2019	If gradable parameter, corresponding evaluation names in NCI-CTCAE 4.03	Worst on treatment value based on normal range
Biochemistry	Albumin	Hypoalbuminemia	LOW
	Aspartate aminotransferase	Aspartate aminotransferase increased	HIGH
	Alanine aminotransferase	Alanine aminotransferase increased	HIGH
	Alkaline phosphatase	Alkaline phosphatase increased	HIGH
	γ-Glutamyl-transferase	GGT increased	HIGH
	Lactate dehydrogenase		HIGH
	Bilirubin (total)	Blood bilirubin increased	HIGH
	Protein (total)		LOW
	Creatinine	Creatinine increased	HIGH
	eGFR	Chronic kidney disease	LOW
	Amylase	Serum amylase increased	HIGH
	Lipase	Lipase increased	HIGH
	Bicarbonate		LOW
	Blood urea nitrogen		HIGH
	Glucose	Hyperglycemia	HIGH
	Glucose	Hypoglycemia	LOW
	Sodium	Hypernatremia	HIGH
	Sodium	Hyponatremia	LOW
	Potassium	Hyperkalemia	HIGH
	Potassium	Hypokalemia	LOW
	Chloride		NA
	Calcium	Hypercalcemia	HIGH
	Calcium	Hypocalcemia	LOW
	Magnesium	Hypermagnesemia	HIGH
	Magnesium	Hypomagnesemia	LOW
	Phosphate	Hypophosphatemia	LOW
	Uric Acid	Hyperuricemia	HIGH
Hematology	Hematocrit		LOW/HIGH
	Hemoglobin	Hemoglobin increased	HIGH
	Hemoglobin	Anemia	LOW
	Red blood cell count		NA
	Mean corpuscular volume		NA
	Mean corpuscular hemoglobin		NA
	Mean corpuscular hemoglobin concentration		NA
	Reticulocyte count		NA

	Platelet count	Platelet count decreased	LOW
	White blood cell count	Leukocytosis	HIGH
	White blood cell count	White blood cell decreased	LOW
	White blood cell differentials and absolute counts: Basophils		NA
	White blood cell differentials and absolute counts: Eosinophils		NA
	White blood cell differentials and absolute counts: Lymphocytes	Lymphocyte count increased	HIGH
	White blood cell differentials and absolute counts: Lymphocytes	Lymphocyte count decreased	LOW
	White blood cell differentials and absolute counts: Monocytes		NA
	White blood cell differentials and absolute counts: Neutrophils	Neutrophil count decreased	LOW
Urinalysis	pH		NA
	Nitrite		NA
	Protein		NA
	Blood		NA
	Glucose		NA
	Ketones bodies		NA
	Urobilinogen		NA
	Bilirubin		NA
	leukocyte esterase by disptik		NA
	Specific gravity		NA
Coagulation	International normalized ratio		NA
	Partial thromboplastin time		NA
Urine Microscopy	White blood cells		HIGH
	Red blood cells		HIGH
	Casts		NA
	Crystals		NA

ELECTRONIC SIGNATURES

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